

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**Coordinating Office for Terrorism
Preparedness and Emergency Response (COTPER)
Board of Scientific Counselors (BSC)**



**Summary Report
August 5-6, 2008**

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Tuesday, August 5, 2008

Call to Order / Welcoming Remarks

Call to Order

Howard Koh, M.D., M.P.H., COTPER BSC Chair
Harvey V. Fineberg Professor of the Practice of Public Health
Associate Dean for Public Health Practice
Director, Division of Public Health Practice
Harvard School of Public Health

Dr. Howard Koh called the meeting to order, acknowledging what a privilege it was to serve as Chair for the very distinguished members of the Board of Scientific Counselors (BSC) for the Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER). He was pleased to welcome the Centers for Disease Control and Prevention's (CDC's) Director, Dr. Julie Gerberding to offer the welcoming opening remarks for this first COTPER BSC meeting.

Director's Welcome

Julie Gerberding, M.D., M.P.H., Director
Centers for Disease Control and Prevention

Dr. Gerberding welcomed those present, expressing her excitement about the convening of the first COTPER BSC meeting. She recognized that the members' agreement to serve on an advisory committee was a tribute to the importance of this effort. She emphasized that the commitment to have CDC's preparedness programs be science-based was viewed as a key principle of operation by the CDC. The CDC's success is based on the science that takes place behind the scenes and which brings an evidence base, confidence, and integrity to make wise decisions that people can trust and respect even under difficult circumstances. Recent news had centered on the alleged conduct of a person who may have been the perpetrator of the 2001 anthrax attacks. The science of CDC was very much in play from that first day in 2001 when consideration was being given to how to diagnose the organism and how to understand its genetic resistance capabilities. CDC's laboratories played a key role in the diagnostic capabilities with respect to molecular fingerprinting, connecting the various outbreaks, environmental sampling, personal protective equipment, communication, and other areas. Nevertheless, Dr. Gerberding stressed that the COTPER Board was in place because there remained gaps in the science.

As CDC moved through the anthrax attacks and their aftermath, a number of after action reviews were conducted. One of the most important concepts that arose was the issue of competency: that there were aspects of science that the agency did not have, and aspects of the way CDC worked in the context of a scientific environment that did not allow for the broad type of instant thinking and learning that was required during an event. For example, there were issues that caused CDC to get off track, such as the dogma that it took 50,000 spores to cause disease, or that anthrax could not be re-aerosolized. There were numerous issues for which there was little known about the science so it was difficult to understand the nature of the threat (e.g., who would be at risk, how fast that risk would unfold, and what else might have been done

to mitigate against risk). Dr. Gerberding stressed that she was not criticizing where the agency was at that time, but wanted to illustrate that being successful truly does depend upon science. She recognized that it was critical to have external advisors who are knowledgeable about what CDC perceives as its goals, objectives, direction, and prioritization of investments, and to inform the agency when it is not on track with how the external community perceives CDC's priorities, performance expectations, gaps, and connections with others (e.g., scientific, academic, or private sector). Input with respect to these areas would be tremendously beneficial contribution that the COTPER BSC could make to the agency.

Dr. Gerberding pointed out that the COTPER BSC members were also convened as part of a broader commitment CDC has made since undergoing a structural reorganization to become a more integrated CDC. A revised CDC policy mandates that all of the agency's intramural programs should be peer reviewed by BSCs. While this has been a tradition in the National Center for Infectious Disease (NCID) for a long time, it has not been normative for the entire agency. Therefore, she made a personal commitment to ensure that all of CDC's science and programs had the benefit of external peer reviews of a caliber at least comparable to the National Institutes of Health's (NIH's) process. The COTPER BSC is to be part of the process of ensuring quality, a standard of excellence, and making recommendations for improvements where necessary. Dr. Gerberding also recognized those who were present from COTPER and the scientific community at CDC, and expressed her gratitude for their support of this effort and the extraordinary work they do.

With respect to the functional anthrax exercise that was underway at CDC at the time of the BSC meeting, Dr. Gerberding assured everyone that it was not timed to correspond to the current newspaper reports, but was a coincidence that unfortunately was bearing an uncanny likeness to some of the issues that were historically noteworthy. She explained that it was a greater than 48-hour functional exercise during which the stockpile actually had been deployed to a particular community, CDC laboratories were testing samples, and critical operational performance exercises were being conducted to ensure that the agency had, indeed, engaged in the learning and the advancement of the agenda.

In conclusion, Dr. Gerberding extended her personal thanks to the COTPER BSC and impressed upon them the importance of their charge. She viewed this endeavor as a new chapter in preparedness for which she hoped CDC would be on the leading edge.

COTPER Welcoming Remarks

**Richard E. Besser, M.D., Director
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention**

Dr. Besser welcomed those present, stressing that Dr. Gerberding had been a strong advocate for establishing the COTPER BSC and recognized that this was an historic day at CDC and for COTPER. COTPER is one of the younger organizations at CDC and as such is learning, growing, and establishing new ways of doing business. He thanked the members wholeheartedly for agreeing to participate on the COTPER BSC and to lend to this review the varied backgrounds they each represented. While CDC historically has had a number of BSCs, he thought the COTPER BSC was unique in terms of the types of disciplines represented (e.g., traditional public health and medicine, engineering, informatics, behavioral sciences, etc.). COTPER is very open to external eyes and to ensuring that they use this opportunity together to help the nation become more prepared. Clearly, enormous improvements have been made in

this country in the area of preparedness; however, much more remains to be done. In addition to the large-scale anthrax exercise, Dr. Besser pointed out that CDC continued to respond to the large Salmonella outbreak that was on-going throughout the nation and to monitor Hurricane Edouard with resources already positioned should they be needed. He pointed out that all of this was being done with systems that did not exist 10 years ago.

In conclusion, Dr. Besser stressed that COTPER looked forward to BSC's engagement, expertise, and guidance.

Overview and Introductions

Howard Koh, M.D., M.P.H., COTPER BSC Chair
Harvey V. Fineberg Professor of the Practice of Public Health
Associate Dean for Public Health Practice
Director, Division of Public Health Practice
Harvard School of Public Health

Dr. Koh explained that the BSC consisted of 10 BSC appointees, 3 voting ex-officio members, and 6 non-voting liaisons. In addition, senior COTPER leaders and other members of CDC and the public were present. He indicated that this was a public meeting for which the minutes would be compiled and ultimately placed on CDC's website. He expressed gratitude to Drs. Sosin and Ellis and their staff that spent a considerable amount of time and effort developing the framework for this meeting. He then reviewed the meeting agenda and ground rules and led everyone in a round of introductions.

Function of the BSC, COTPER

Dan Sosin, M.D., M.P.H., Designated Federal Official
Director, Biosurveillance Coordination Unit
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

On behalf of CDC, COTPER, and the federal government, Dr. Sosin extended his welcome and gratitude to those present for their commitment to doing this hard work. He explained that his role as the Designated Federal Official (DFO) for the COTPER BSC was to serve as their point of contact, tour guide, and research assistant in order to ensure that the Chair and the Board received what they needed in order to fulfill their charge.

Dr. Sosin read the following excerpt from the COTPER [BSC Charter](#) with respect to their function, "The Board of Scientific Counselors, Coordinating Office for Terrorism Preparedness and Emergency Response, shall advise the Secretary, HHS, and the Director, CDC, concerning strategies and goals for the programs and research within the divisions; shall conduct peer-review of scientific programs; and monitor the overall strategic direction and focus of the divisions. The board, after conducting its periodic reviews, shall submit a written description of the results of the review and its recommendations to the Director, CDC. The board shall perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the coordinating office." Dr. Sosin pointed out that while most of this meeting would focus

upon orientation and the peer review process for intramural peer review, COTPER has an extramural research program that was begun in 2008 for which it was expected that the COTPER BSC would serve in the function of secondary and other related science review activities in accordance with the charter. Beyond the explicitly stated purpose, the goal of the BSC would be to create and support a transparent, multi-disciplinary process for expert review, advance COTPER's capacity to improve its processes, programs, and provide vision through science-based input from the BSC to the Directors of COTPER and CDC. The BSC's recommendations would ensure that COTPER's programs, wherever possible, would be grounded in science and that COTPER would evaluate and implement evidence-based practices, protocols, and policies to improve its national and international role in emergency preparedness and response.

The science base for public health emergency preparedness is broadly distributed across many disciplines, which Dr. Sosin pointed out, was reflected in the make-up of the COTPER BSC. Recognizing the numerous gaps in the science and the problems for which they are preparing, COTPER was asking BSC members to share their scientific knowledge and relate it to COTPER through targeted reviews. While no one is bestowed with the entirety of human knowledge, Dr. Sosin acknowledged that the BSC's best efforts to inform COTPER programs and practices from the perspective of deeply trained and experienced scientists would serve everyone well. As Drs. Gerberding and Besser suggested, COTPER's work would be an open book to the BSC as they sought thoughtful science-based guidance in order to best utilize COTPER's resources.

In conclusion, Dr. Sosin introduced Diane Manheim, Coordinator for the COTPER BSC. He also expressed his regret that he would not be able to attend the second day of the meeting; however, he indicated that Dr. Ellis would serve in his place, and acknowledged that for the past seven months, Dr. Ellis had served as the DFO for this work and as the Acting Associate Director for Science in COTPER, given his work on related and important activities pertaining to biosurveillance.

COTPER Overview Presentation

Richard E. Besser, M.D., Director

**Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention**

Dr. Besser offered an overview of COTPER and of CDC's preparedness and emergency response efforts. CDC is presently engaged in a very exciting activity known as the "Healthiest Nation Alliance." This activity is being conducted in conjunction with other governmental public health organizations, such as the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO), in an effort to address the challenge faced in the United States of spending more per capita than any other country on health, with health outcomes not at the highest level. Through this initiative, particularly as the nation faces a political transition, there are opportunities to move forward to create a true "Healthiest Nation."

A healthy nation fares better during a public health emergency. For example, those impacted the most by Hurricane Katrina were individuals with chronic diseases and those who were not empowered to make health decisions for themselves. Becoming a Healthiest Nation will make

communities more resilient and better able to deal with public health threats and emergencies. The focus of the alliance is to promote and sustain health in a broader context than health care and health reform; enact health in all policies, creating opportunities to integrate health considerations into societal policies across sectors and at all levels; and to execute health protection goals to achieve greater health impact by focusing on priorities and needs identified by CDC in its Goal Action Plans and portfolio analyses. CDC organizes its activities around four overarching health protection goals: Healthy People in all Stages of Life, Healthy People in Healthy Places, Healthy People in a Healthy World, and People Prepared for Emerging Health Threats.

Dr. Besser wanted to acknowledge that CDC recognizes the enormous burden of chronic diseases and other health issues. However, COTPER focuses on urgent threats: infectious diseases, new and emerging infectious diseases, on-going large-scale food borne outbreaks, pandemic threats, deliberate threats (like the World Trade Center in 2001 and the following anthrax attacks), and natural disasters.. Concerns have also been raised about climate change and the possibility that this will lead to increasing threats of natural disasters. Concerns have also been raised about climate change and the possibility that this will lead to increasing threats of natural disasters.

CDC does not view preparedness as an end state, but rather is the continuous process of improving the health system's capacity to detect, respond to, recover from, and mitigate the consequences of terrorism and other health emergencies. The agency's over-arching preparedness goal is that people in all communities will be protected from infectious, occupational, environmental, and terrorist threats. CDC is cognizant of the fact that public health protection in an increasingly smaller world requires fast detection, fast science, fast and effective communication, fast and effective integration, and fast and effective action. The process that COTPER will go through with the BSC will hopefully improve CDC's systems, speed, and readiness.

CDC and COTPER are also aware that preparedness is not just about public health but also a much broader system and networks of shared responsibility for protecting the public's health. This network includes federal and local governmental systems, domestic and international systems, public and private partnerships, animal and human health, and partnership across multiple sectors. CDC does not operate on its own—it is part of a much larger framework. CDC's work in preparedness supports the Department of Homeland Security (DHS), which has overall authority for emergency response activities as laid out in the National Response Framework (NRF); and the Department of Health and Human Services (HHS), which under the NRF has responsibility for Emergency Support Function 8, public health and medical services. There have been a number of recent Legislative and Presidential Directives that have impacted on the focus of CDC's work. This includes the Pandemic and All-Hazards Preparedness Act, passed in December of 2006. This placed HHS as the lead agency for public health and medical response. It also drove a number of programmatic changes and advances within CDC. In addition, Homeland Security Presidential Directive 21 (HSPD – 21; October 2007) legislates that HHS lead federal efforts regarding national biosurveillance strategy and medical countermeasure distribution. Dr. Sosin is the lead in this effort for CDC, and is also the lead across the federal government for the activities to develop a biosurveillance strategy.

CDC takes an all-hazards approach to preparedness and response. Although the agency's resources frequently are categorical (e.g., significant funds for pandemic flu, significant funds for terrorism), CDC knows that the systems underpinning its preparedness and response for various scenarios are basically the same. The all-hazards approach prepares for a multitude of

events through information systems, training, planning, communications, and readiness. Experience has shown that preparing for and responding to one type of event can also help to prepare for and respond to other events. All-hazards preparedness and response encompass biological, nuclear, radiological, trauma, chemical, and natural events. The all-hazards approach also allows federal, state, and local partners to maximize the limited resources available for preparedness and response programs.

COTPER is one of six coordinating offices or coordinating centers within CDC, which were established through CDC's organizational restructuring as part of the Futures Initiative. COTPER's work is vertical in terms of its own programs and horizontal working across the agency. Within COTPER, there are five divisions, four of which are programmatic: Strategic National Stockpile, Select Agents and Toxins, Emergency Operations, and State and Local Readiness. There are six offices within COTPER's Office of the Director: Office of Science and Public Health Practice, Department of Defense (DoD) Liaison, Workforce and Career Development Office, Enterprise Communication Office, Learning Office for Preparedness & Response, and Strategy and Innovation Office.

COTPER's vision for preparedness is simple: People protected—public health prepared. COTPER's new proposed mission statement is: We safeguard health and save lives by providing a flexible and robust platform for public health emergency response. Emerging from this mission are four strategic themes, which are to build internal response capabilities at CDC; build external response capabilities, primarily in state and local public health; connect COTPER within CDC and build connections outside of COTPER; and optimize the resources received. At present, COTPER receives about a quarter of CDC's budget. Thus, it is absolutely critical that reviews be undertaken in order to ensure that COTPER is directing those funds in the most effective way possible. Strategic activities in support of these themes are to provide strategic direction on preparedness as well as training and education to CDC; allocate terrorism preparedness resources across CDC; ensure program accountability by integrating budget and performance; serve as point of contact on preparedness for key stakeholders; promote progress through public health science; and report on progress and challenges in public health preparedness. Critical operational activities are to manage CDC's Public Health Emergency Preparedness Cooperative Agreement, which funds state and local preparedness efforts; manage the Strategic National Stockpile (SNS) and critical medical assets; manage CDC's emergency response operations through the Director's Emergency Operations Center (DEOC); and manage the regulation of the possession, use, and transfer of select agents (SAs) to protect public health and safety.

Dr. Besser briefly reported on the offices within COTPER. The Learning Office for Preparedness and Response (LOPR) headed by Andrea Young develops and executes CDC preparedness and response learning strategy. It provides oversight and coordinates analysis, design, development, implementation, and evaluation of workforce development programs for internal and external responders. This includes the development of competency-based curriculum for CDC responders; meta-leadership development activities, including a program in conjunction with Harvard and a national roll-out of programs; training programs with schools of public health, including the Centers for Public Health Preparedness (CPHP); and activities related to planning and implementation of Pandemic and All-Hazards Preparedness Act (PAPHA / HSPD-21) core curricular activities.

The Workforce and Career Development Office (WCDO) headed by Deborah Gould provides oversight and coordination for planning, developing, implementing, and evaluating workforce development programs that target the COTPER workforce. This office is responsible for

workforce analysis and planning processes for COTPER, and assesses employee satisfaction through an annual survey. This office also advises on agency-wide workforce and career development policy, strategy, and programs.

The Office of Science and Public Health Practice (OSPHP) headed by Barbara Ellis has experienced major growth and is part of the drive to integrate science into all that COTPER does. The office provides scientific advice, guidance, and leadership to the COTPER director, senior leadership in the divisions and offices, and the COTPER staff. The office is responsible for oversight of scientific activities within COTPER, and advocates for its scientists and the scientific basis of its programs. OSPHP is committed to increasing scientific contributions to the preparedness and response knowledge base, and to promoting the translation of science to practice. OSPHP is overseeing the launch of a new external research program, and the establishment of five to seven Centers for Public Health Preparedness (CPHPs). The office also has within it the Career Epidemiology Field Officers, nearly 30 mid-level epidemiologists who are based throughout the country supporting state and local public health. The office also interacts with CDC's Public Health Ethics Committee (PHEC) and has taken a lead role in developing ethical guidelines for preparedness and response.

The Enterprise Communication Office (ECO) headed by Ann O'Connor bridges the responsibilities of policy and communication professionals across CDC, working collaboratively with CDC experts in science, public health, policy, and communications. This office provides leadership in managing urgent high-profile issues, media relations, and internal communications. ECO also leads the coordination of reviews by the Office of the Inspector General (OIG) and Government Accountability Office (GAO), and Freedom of Information Act (FOIA) requests, and controlled correspondence. They ensure consistent, accurate, and comprehensive messaging across all activities, and are also the lead office within COTPER for the COTPER preparedness report.

The Strategy and Information Office (SIO) headed by Stephanie Zaza serves as the focal point for long-range planning and policy development. This office develops and articulates strategy, aligns budget to strategy, and integrates budget and performance. The SIO also integrates a functional framework for public health emergency preparedness and response into strategy, budget, performance measurement, and communications.

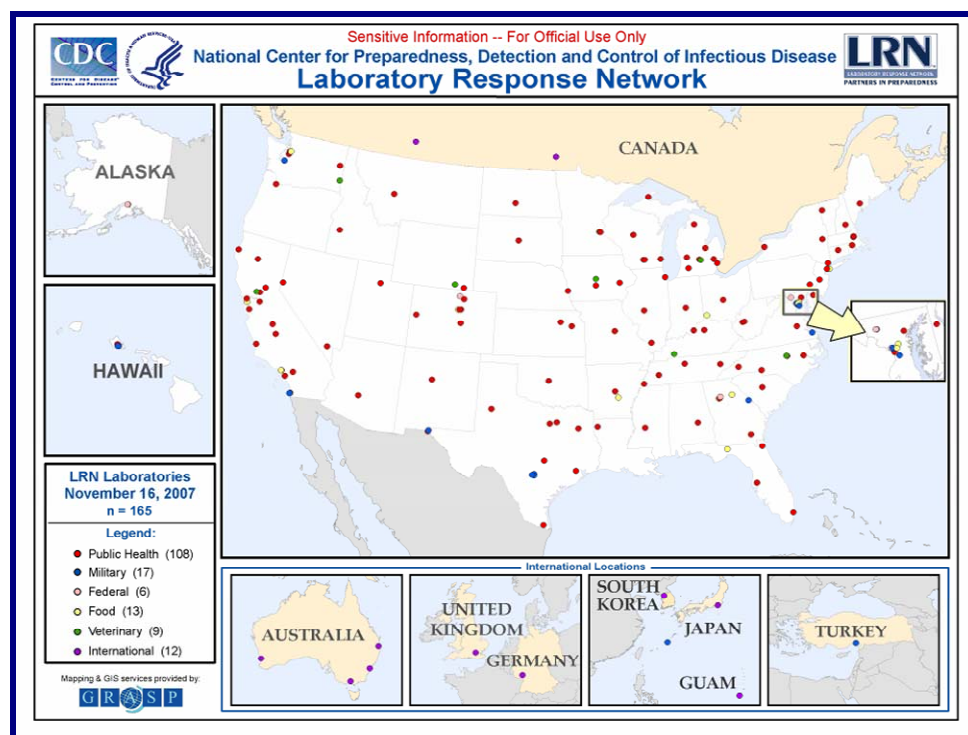
The Department of Defense (DoD) Liaison Office headed by Colonel Cieslak enhances collaboration between DoD and CDC regarding protection from adverse natural and intentional health impacts; staffs the DoD seat in DEOC, provides links to DoD assets and expertise; provides clinical and public health outreach; and coordinates mutual CDC and DoD efforts such as surveillance and SA activities. While Colonel Cieslak is housed in COTPER, he serves the entire agency as the liaison to the DoD.

Regarding COTPER's four largest tactical activities, Dr. Besser reported that the Public Health Emergency Preparedness Cooperative Agreement is managed by the Division of State and Local Readiness (DSLRL) for which Donna Knutson is the Acting Director. DSLRL provides guidance and funds to state, local, territorial and tribal health departments to strengthen preparedness. In FY08, \$705 million were awarded through this cooperative agreement. The division provides technical assistance and consultation, and develops performance metrics and gathers performance data on exercises and real events. The Strategic National Stockpile (SNS), headed by Greg Burel, manages and maintains the repository of critical medical assets including antibiotics, antivirals, antitoxins, other life-support medications, and supplies. It procures, stores, and delivers these assets to a site of a public health emergency; and provides

technical assistance to help move medical assets from warehouses to points of dispensing through federal, state, and local efforts. The Director's Emergency Operations Center (DEOC) is managed by the Division of Emergency Operations, with Phil Navin serving as the director. It functions as the command center for coordinating emergency responses to domestic and international public health threats. The DEOC coordinates CDC's preparedness, assessment, response, recovery, and evaluation for public health emergencies, and serves as the point of contact for state agencies reporting potential public health threats. The Select Agent Program (SAP), which is managed by the Division of Select Agents and Toxins (DSAT) and is headed by Dr. Rob Weyant, regulates all entities that possess, use, or transfer biological agents or toxins that could pose a severe threat to the public. It is designed to ensure compliance with select agent regulations by providing guidance to registered entities and conducting evaluations and inspections. This is truly a collaborative activity jointly run with the United States Department of Agriculture (USDA) and the Department of Justice (DOJ) to protect public health by ensuring laboratory biosafety and security among facilities working with select agents. This collaboration is essential to the success of the program.

With respect to biosurveillance, Dr. Besser reported that CDC was designated as the lead federal agency for coordinating the development of the National Biosurveillance Strategy for Human Health (2007), which is a part of HSPD-21. The strategy being developed must strengthen public health practice, provide value to clinicians, and build upon current systems and resources. Dr. Gerberding established the Biosurveillance Coordination Unit (BCU) as a way of taking on this extraordinary challenge, and Dr. Sosin has been heading that since January 2008 when it was established. A draft strategy is currently out for review, which attempts to examine the wide array of biosurveillance activities and identify gaps. CDC is currently focusing on the following select programs for enhancing biosurveillance activities: BioSense, a system that connects real-time or near real-time health information for public health action; BioPHusion, to merge health information with other sources of information to provide rapid information for decision making; Global Disease Detection, to build infrastructure and build upon existing infrastructure internationally to detect and respond to health threats outside of United States borders faster; and BioWatch in collaboration with DHS and the Environmental Protection Agency (EPA), in which CDC participates primarily through the Laboratory Response Network (LRN). CDC maintains situational awareness of public health threats through the use of multiple biosurveillance capabilities that are components of a wide range of public health programs. These biosurveillance activities rely on a skilled workforce to collect, analyze, and interpret data from clinical and public health practice activities; adaptive approaches to electronic health information technology; and laboratory capability to rapidly verify exposures and diseases and communicate results for public health action.

Some of the core components include the LRN, which is funded through the preparedness line item. This is an extraordinary national network of hospitals and testing laboratories (part of state and local public health, federal, military, veterinary, agricultural, food and environmental). This system provides laboratory diagnostic capacity to respond to biological and chemical terrorism and other public health emergencies. Before the LRN was in place, the time it took to verify and validate results occurring throughout the country seriously delayed response. The current system allows CDC to trust the results received. Laboratories are using the same assays and are all participating collaboratively in proficiency testing. PulseNet is another laboratory surveillance system that provides the capability for quick comparison of the genetic subtypes on a molecular level for detection of food borne outbreaks. For example, this system was critical to identifying recent multi-state outbreaks of *Salmonella* Saintpaul and *E. coli* O157:H7. There are currently >160 LRN laboratories, with 90% of the United States population living within 100 miles of an LRN laboratory:



CDC is also engaged in a great deal of work regarding "just in time" information and education. Some of the systems that are supported through preparedness funds include the Epi-X system, which is a system used for confidential communication between epidemiologists; the Health Alert Network (HAN), which is how CDC distributes warnings about urgent health threats; the *Morbidity and Mortality Weekly Report (MMWR)*, which is CDC's longest standing means of health communication that can now publish very rapid communications electronically; public health web pages on emergency preparedness and response, including Spanish language pages; satellite broadcasts; hotlines for clinicians and the public; and a wide array of podcasts, webcasts, and videos on CDC's website.

One of COTPER's critical functions is reporting, which is absolutely essential to all that COTPER does. The BSC will be called upon for input about how COTPER can do a better job of measuring its progress and communicating that externally. COTPER is committed to presenting an increasingly clear picture of public health preparedness in the U.S. The first report was published in February 2008 on state preparedness activities funded through the Public Health Emergency Preparedness Cooperative Agreement. The next report will be published in September 2008 on COTPER investments across CDC in terrorism preparedness and emergency response. COTPER is clearly limited by the quality of measurement tools currently available, but has made a large investment in the effort to develop better metrics for measuring preparedness.

In conclusion, Dr. Besser compared CDC's current preparedness to the past. He reported that in 2001 there were 115 epidemiologists working in emergency response. In 2006, that number had more than doubled to 232. Before 1999, CDC performed all confirmatory testing for biological agents for the federal public health system. Currently, there are over 160 public health laboratories throughout the country. Before 2003, CDC performed all the confirmatory testing for chemical agents. Currently, CDC's LRN for Chemical Terrorism includes 62 laboratories, of which 47 can perform definitive tests for selected chemical agents. In terms of response and recovery, for the anthrax investigations in 2001, CDC headquartered its response activities in a conference room. Currently, the DEOC has dedicated staff to monitor emerging public health threats 24/7/365. In 1999, CDC created the SNS as part of the nation's preparation for potential incidents related to Y2K. Today, the SNS stands ready to respond to a wide variety of threats.

Discussion:

Dr. Jack Harrauld pointed out that faster systems required a different decision-making process, a different understanding, acceptance of uncertainty, and a different acceptance and understanding of completeness of information. He wondered how that was unfolding.

Dr. Besser responded that at CDC and across public health, this represented a culture change in terms of learning to make rapid decisions and to act with incomplete information. Having trained at CDC as an Epidemic Intelligence Service (EIS) Officer, and coming from an academic background, he was taught a very academic approach (e.g., ensure that everything is right before acting). While they wanted to be right, for the types of disasters and emergencies that face society currently, they must learn to be comfortable with moving fast and not to wait to be 100% certain. In an anthrax scenario in which antibiotics must be administered to an affected population within 48 hours, it cannot take 48 hours to make a decision about whether to send the stockpile and whether to start prophylaxis. The new systems in place are helping to achieve rapid response, but different training will likely be required as well.

With respect to biosurveillance, Professor Sharona Hoffman wondered to what extent electronic medical records (EMR) would be important.

Dr. Sosin replied that EMRs would be very important. Based on experience with exploration of complementary data sources, information that comes through the health system is the most specific and accurate for the purposes of public health surveillance and emergency response.. EMRs, automated case recognition tools, and other such technologies to facilitate that bridge between public health and clinical medicine are perceived as complementary and enhancing .

Dr. Robert Ursano requested further information regarding BioPHusion and rapid decision-making tools and modeling.

Dr. Sosin acknowledged that they are awash in information and need to better filter, triage, and utilize that information. The idea is to figure out how to use the law enforcement fusion concept in the public health arena making better connections so that the information available from different sources becomes more broadly accessible in a timelier manner. The concept of BioPHusion was a priority of the CDC director, who created an Office of Critical Information Integration and Exchange (OCIIIX) to start a BioPHusion program. OCIIIX is in the early phases of determining what a fused report would look like, and what tools are available to help decision makers examine information more quickly and accurately. Modeling is an important component of this effort (e.g., bringing all inter-agencies together to use the same tools, apply the best science). CDC is not alone in this work. They are working with DHS and the National Biosurveillance Integration System.

With regard to the institutional framework, Dr. Margaret Hamburg wondered whether there was a mechanism to ensure coordination of activities and decision making with the private sector and other critical partners for preparedness and response.

Dr. Besser replied that the private sector is an underutilized resource and player in preparedness and response. In many program areas, COTPER is working to engage the private sector. Examples include the DEOC, which has a desk that has been staffed at times by business executives for national security that can help tap into some of the business sector assets that are available. The CDC Foundation has tapped into the private sector during many response activities for resources and response. The area in which COTPER has done the most in terms of integrating and working with the private sector is with the SNS in terms of private sector enhancements to the system. Moving materiel from its secure locations to states is done through private sector contracts, for example. Approximately 80% of states have contracts and formal relationships with private sector partners to assist in some aspect of countermeasure distribution. The Institute of Medicine (IOM) Forum has been a great mechanism to engage private sector entities. HHS has been working diligently to address some of the private sector liability concerns about getting involved further. The Preparedness Act provides another opportunity for private sector engagement.

Mr. Bill Stephens applauded the stunning array of improvements that have been brought to bear on various threats over the last seven years. He also requested further information regarding nuclear and radiological efforts.

Dr. Besser responded that with regard to nuclear and radiological issues, there were critical gaps and challenges in terms of preparedness and response. COTPER is providing resources to CDC's National Center for Environmental Health (NCEH), which is in the process of developing high throughput assays to be used in the event of a radiological emergency. However, the assays are not ready to take to scale. Resources received for radiological preparedness have been rather disappointing. In the past year, COTPER invested close to \$10 million in radiological preparedness, but it was at the expense of other preparedness and response programs. While the President's recent proposed budget included \$10 million for radiological / nuclear preparedness, it was not in either the Senate or House budget. While clearly this is an area in which more must be done, Dr. Besser stressed his reluctance to build nuclear preparedness at the expense of biological, chemical, or other preparedness systems.

Dr. Ellen MacKenzie inquired as to what extent COTPER would be involved in response to physical trauma resulting from conventional explosions, other kinds of terrorism, and natural disasters.

Dr. Besser replied that COTPER would be conducting a tabletop exercise in October to better understand its role in that setting. CDC will have a role in responding to blast events, but he thought that response would rest primarily with the Assistant Secretary for Preparedness Response (ASPR) where the National Disaster Medical System (NDMS) is located. COTPER allocated resources to a division within CDC's National Center for Injury Prevention and Control (NCIPC) that develops "just in time" training materials used in various settings, and which oversees a network of emergency physician specialists in the area of trauma.

Dr. Koh asked Dr. Besser to comment on what CDC and COTPER had done well in terms of defining their current and future roles compared to all of the other forces involved in the response network in this country.

Dr. Besser replied that this is an on-going challenge. As various systems have been built up, there is frequently friction as they grow and intersect. However, it is critically important to exercise together, work together, and understand roles and responsibilities. There are intensive exercise programs in place that help to do that. In speaking to many colleagues at the state and local levels, there is clearly a need for better clarity in terms of the responsibilities of DHS, ASPR, and CDC and how they all work together. Continued work is needed in this area.

Dr. Damon Arnold wondered how COTPER would be involved in the development of policy, for example, with respect to its role with the laboratories. Given that it appeared that laboratory identifications were being made primarily by external laboratory systems, it seemed some form of policy would be needed to drive the analyses of the results back to CDC.

Dr. Besser responded that the LRN is a well-governed organization. The Integrated Consortium of Laboratory Networks (ICLN) provides some governance in this arena. Certain types of analyses will be conducted at CDC that cannot be done at the local level; however, primary identification will rest at the local level. CDC will still want to receive isolates in order to conduct resistance testing and genetic analyses, but if an LRN laboratory says an isolate is anthrax, CDC will take action at that point without waiting for follow-up.

Dr. Hamburg asked what the procedure would be in the event of an agent that requires Level 4 laboratories..

Dr. Besser responded that he would have to report back to the group on what the formal procedure would be. CDC has the ability to rapidly transport samples by sending a CDC airplane to pick up critical specimens. In the last couple of years, there was a cluster of people with unknown neurologic syndrome in Panama. CDC deployed a team to assist with that. When the airplane returned, it brought samples back to CDC so that testing could be conducted in the NCEH laboratories. CDC has BSL-4 facilities to handle such specimens as necessary.

Dr. Koh expressed his gratitude to Dr. Ellis, who worked for months in planning this meeting.

COTPER Preparedness Resources

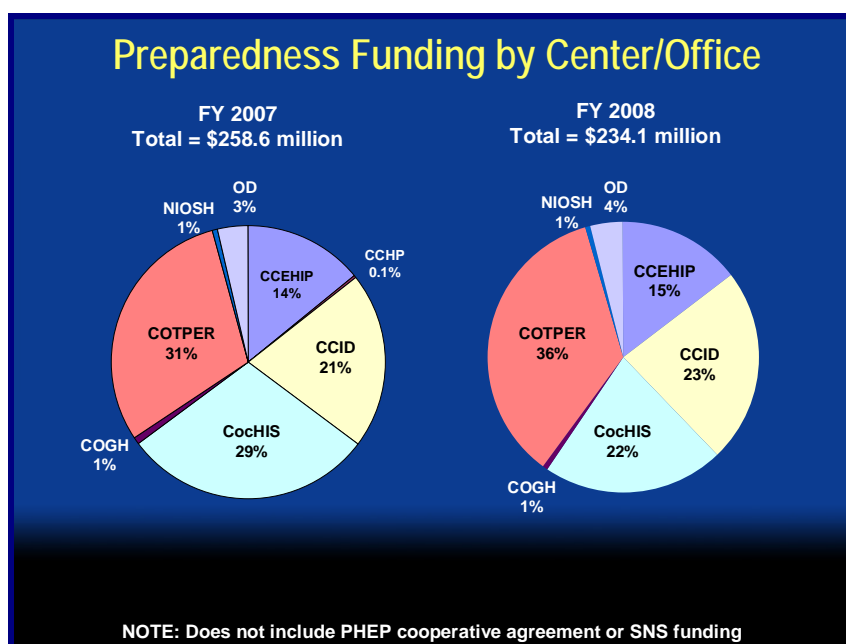
Stephanie Zaza, M.D., Strategy and Innovation Officer
Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)
Centers for Disease Control and Prevention (CDC)

Dr. Zaza presented an overview of COTPER's strategy concerning CDC's preparedness budget and COTPER's stewardship of that budget. She focused on how COTPER makes high-level decisions about allocating these resources across the agency and within COTPER rather than how resources are allocated once they leave CDC (for example, when they go to states, major metropolitan areas, and territories through the Public Health Emergency Preparedness cooperative agreement). While this is a large budget, Dr. Zaza stressed the importance of understanding that the funding is restricted in terms of how it can be used. Further, the agency's expanding program scope and strategic needs for public health preparedness, coupled with limited resources, emphasizes the importance of thoughtful and targeted investments.

Some of CDC's major budget lines include infectious disease (including pandemic flu), health promotion, health information and service, environmental health and injury prevention, occupational safety and health, global health, preventive health and the health services block grant, preparedness, and other enterprise-wide lines (e.g., public health research, public health improvement and leadership, buildings and facilities, business service support). Until 2002, there was not a large or dedicated terrorism preparedness budget line. CDC currently receives \$1.6 billion specifically for preparedness (approximately 18% of CDC's total budget of about \$9 billion in fiscal year 2008). Of that, \$155 million is part of the pandemic influenza supplement that is managed by the Coordinating Center for Infectious Diseases. Dr. Zaza reported on the \$1.5 billion that is managed by COTPER, which breaks down as follows:

| "Preparedness" Budget | | | |
|---|-----------------------------|------------------------|-----------------------|
| | FY2007 (enacted) | FY 08 (enacted) | FY 09 (PB) |
| Upgrading State and Local Capacity | \$766.7 | \$746.0 | \$609.4 |
| -PHEP Cooperative Agreement | \$712.9 | \$700.5 | \$570.9 |
| -Centers for Public Health Preparedness | \$29.1 | \$28.6 | \$28.5 |
| -Advanced Practice Centers | \$5.4 | \$5.3 | \$0 |
| -All Other State and Local | \$19.3 | \$11.8 | \$10.0 |
| Upgrading CDC Capacity | \$122.9 | \$120.7 | \$131.1 |
| Anthrax | \$12.4 | \$7.9 | \$7.9 |
| Botulinum Toxin Research | \$3.0 | \$0 | \$0 |
| Biosurveillance | \$71.2 | \$63.1 | \$100.6 |
| -BioSense | \$52.0 | \$34.4 | \$49.9 |
| -Real Time Lab Reporting | \$9.2 | \$9.0 | \$7.5 |
| -Quarantine | \$10.1 | \$9.9 | \$43.3 |
| Strategic National Stockpile | \$496.3 | \$551.5 | \$570.3 |
| Total | \$1,472.6 | \$1,479.4 | \$1,419.3 |

As reflected in this breakdown, large portions of the COTPER budget are pre-directed by Congress in terms of how they will be spent. In fiscal year 2007, this preparedness funding was approximately \$1.47 billion. In fiscal year 2008, it was approximately \$1.48 billion. Of this funding, approximately 91% is pre-directed, primarily by Congress, to specific programs or priorities, and approximately 9% is not (i.e., in the latter instance COTPER and CDC leadership can make decisions about how the funds are distributed). A substantial portion of this budget is not spent on COTPER programs and is used across the agency. Removing the two largest portions of the preparedness budget (e.g., about 85% of the total for the Public Health Emergency Preparedness (PHEP) cooperative agreement program that goes out to state, local, and territorial public health departments, and the Strategic National Stockpile (SNS)), preparedness funding by coordinating center / office is as follows:



CCEHIP: Coordination Center for Environmental Health and Injury Prevention

CCID: Coordinating Center for Infectious Diseases

CoCHIS: Coordinating Center for Health Information and Service

CCHP: Coordinating Center for Health Promotion

COGH: Coordinating Office for Global Health

NIOSH: National Institute of Occupational Safety and Health

OD: Office of the Director

The proportions that go to each organization have not changed dramatically from year to year. There was a slight increase for COTPER, as the preparedness budget is COTPER's only source of funding. In contrast, all of the other coordinating centers/offices have funding lines outside of the supplemental preparedness funding. As COTPER's requirements have grown in terms of new mandates, the amount kept within COTPER increased. The programs COTPER will bring to the COTPER BSC for review will largely be limited to those that are managed and directed within COTPER. Projects funded by the preparedness budget to other centers and office will be reviewed by the BSCs of those organizations. In fact, several preparedness-specific reviews have already been undertaken by those boards. That would not, however, preclude review of cross-center work.

As noted by Dr. Besser, COTPER's operational activities include the Public Health Emergency Preparedness cooperative agreement program, the Director's Emergency Operations Center, the Select Agent Program, the Strategic National Stockpile, agency-wide preparedness and leadership, curriculum development and training programs, extramural preparedness research program, and preparedness strategic planning. As the division directors would present on these programs, Dr. Zaza focused on preparedness strategic planning and how COTPER makes decisions about how the preparedness budget is distributed across the agency. Given the magnitude of this operational responsibility, Dr. Zaza expressed hope that the COTPER BSC would review this effort in detail in the future to make recommendations for improvement.

In terms of funding priorities and how COTPER plans its budget to those priorities, CDC has organized all of its work into four overarching goal areas and associated goal action plans: Preparedness, People, Places, and Global. The Preparedness Goal Action Plan includes nine goals, five functional objectives, a series of sub-objectives under each of those, and a number of strategies. The nine preparedness goals are oriented into Pre-Event (e.g., detect and report), Event (e.g., investigate and control), and Post-Event (e.g., recover and improve). This categorization of the goals has been useful for talking with general emergency management and Homeland Security audiences because it is time-oriented. However, one of the challenges is that these goals affect each other in complicated ways, making it difficult to use them as a planning framework. In addition, the goals are outcome-oriented and should be measurable with the right data systems in place. Another major challenge is how to measure performance in an all-hazards way, when many measurement efforts will require specificity depending upon the scenario.

Unlike most strategic planning efforts, the functional objectives in the preparedness goal action plan do not have a one-to-one relationship with the goals. Instead, these objectives reflect the core functions and capabilities of CDC (see below).

CDC Preparedness Goal Action Plan Objectives

- **Health Monitoring and Surveillance**
Integrate and enhance the existing surveillance systems at the local, state, national, and international levels to detect, monitor, report, and evaluate public health threats.
- **Epidemiology and Other Assessment Sciences**
Support and strengthen human and technological epidemiologic resources to prevent, investigate, mitigate, and control current, emerging and new public health threats and to conduct research and development that lead to interventions for such threats.
- **Public Health Laboratory Science and Service**
Enhance and sustain nationwide and international laboratory capacity to gather, ship, screen, and test samples for public health threats and to conduct research and development that lead to interventions for such threats.
- **Response and Recovery Operations**
Assure an integrated, sustainable, nationwide response and recovery capacity to limit morbidity and mortality from public health threats.
- **Public Health System Support**
Expand and strengthen integrated, sustained national foundational and surge capacities capable of reaching all individuals with effective assistance to address public health threats.

Referring to a question posed earlier by Dr. Koh regarding CDC's role in preparedness as an agency compared to all of the other agencies, Dr. Zaza pointed out that COTPER feels strongly that these five functional objectives grow out of CDC's core objectives as a public health agency, and that these are the functions of CDC that make it unique within the HHS. CDC's work to further define these functions as the agency's lanes for preparedness will help to define CDC's role and clarify where the agency can act and should have leadership responsibility. This work does not, however, obviate the need to make efforts in other areas as well.

A challenge of the preparedness goal action plan is that it is a CDC-wide goal action plan—it does not belong to COTPER, although COTPER is responsible for leading development and ongoing updates. In fact, each organization is currently undergoing a series of processes to define its vertical strategic plan (within in coordinating office/center) that contributes to the horizontal preparedness goal action plan (CDC-wide). As mentioned, COTPER has specific operational responsibilities that are part of its own strategic plan. However, COTPER also must understand the contributions of other coordinating centers/offices at CDC and appropriately distribute funding to agency-wide priority activities.

With respect to how those funding decisions are made, COTPER has identified five tactics as critical for implementing the goal action plan:

- 1) Formulate a budget request through an established process that includes submitting information through HHS and the Office of Management and Budget (OMB). That request is incorporated into the President's budget, and eventually COTPER is asked to write a justification to Congress for their consideration.
- 2) Plan the enacted budget to the existing strategy.
- 3) Execute the budget through funding and implementing programs.
- 4) Measure performance through an established accountability reporting system.

- 5) Continuously engage partners inside and outside of the agency to understand, contribute to, and align activities to the strategy.

Given the time restrictions of this meeting, Dr. Zaza focused on the second step of this process. Budget planning and allocation is done in five stages:

- 1) Pre-Planning and Priority Setting;
- 2) Call for Proposals/Guidance;
- 3) Primary Review Process,
- 4) Secondary Review / Selection Process; and
- 5) Communication of Results.

For the 2009 budget, in March 2008 COTPER began the process of pre-planning and priority setting. CDC has an enterprise-wide system known as HealthImpact.net, in which the entire agency enters all of its plans for the next fiscal year every spring and early summer. COTPER has taken advantage of this database to use it as a way for groups to submit proposals for continuing or new funding. Once proposals are received, COTPER conducts two levels of review (a management review for ongoing projects and a competitive review for new or sensitive projects), with primary reviews using reviewers from across the agency, a secondary review process and selection, and then communication of results.

COTPER's fiscal planning process is unique. No other organization at CDC receives a cross-cutting budget and subsequently distributes it across the agency. COTPER has attempted to streamline this process by examining the types of activities being funded. The first distinction is to pre-plan continuing activities and set priorities for new activity proposals.

The first set of continuing activities to be addressed are those that are funded from the 91% of the budget that is Congressionally stipulated. The second set consists of continuing operations (e.g., funding for the Division of Emergency Operations). The third set consists of continuing short-term research or other projects (e.g., water decontamination research). COTPER believes that once it makes a commitment to a multi-year project, funding should continue as long as the recipient is performing appropriately. However, COTPER takes care to review these multi-year projects to ensure that it is not funding something that needs to be discontinued. Past performance and sensitivity issues are evaluated to identify how these continuing activities will be reviewed once they come in.

All Congressionally-stipulated activities and those continuing activities that are well performing and do not have major sensitivity issues are included in the management review process. This review assures that activities funded from this portion of the budget are properly planned, but does not subject them to the rigorous competitive review process given that COTPER is mandated to allocate these funds in a particular manner. Continuing operations or projects with past performance problems are put into a more stringent competitive review process. The competitive review process also is used for all new proposals, such as the Anthrax Immunoglobulin Safety Database that was submitted for FY09.

In addition to pre-planning the continuing activities, priority setting for new activities is led by the Goal Action Planning Team and the Goal Champions. This includes Dr. Besser, Dr. Henry Falk (Coordinating Center for Environmental Health and Injury Prevention), and Dr. Mitch Cohen (Coordinating Center for Infectious Diseases), who identify the agency-wide priorities developing a sequential priority identification from that Goal Action Plan. COTPER then identifies those priorities that are most appropriate for the use of the preparedness funding line, and subsequently request proposals for those priority areas. COTPER provides written

guidance, engages in consultations across the agency, provides technical assistance, screens the submitted proposals, and generally has to make numerous requests for additional, more complete information or materials that were not submitted.

The proposals that do not require a competitive review go through a management review. Management review occurs for on-going programs that have had minimal or no past performance problems, and have minimal or no sensitivity issues (e.g., little media interest or public inquiry). Competitive reviews are typically conducted for continuing projects that have a lot of performance or sensitivity issues, and for all of the new proposals. Dual reviews are conducted by senior scientific and programmatic staff within COTPER, using a standard scientific criteria review set with review questions. This process is a major endeavor. For FY09 there were approximately 95 projects under management review, and approximately 80 under competitive review.

The secondary review process is new this year. It will include a panel comprised of representatives from COTPER, CCID, CCEHIP, and the Coordinating Center for Health Information and Services. The merit-based primary review results (from both the management or competitive review processes) will be provided to the secondary review panel, which will consider merit, past performance and funding history, priority alignment, and priority rankings provided by each Coordinating Center/Office. The ultimate goal is to reconcile the panel reviews and recommendations and to develop a consolidated set of recommendations for Dr. Besser's consideration. Once selections are made, the results are communicated through briefings to key stakeholders; individual meetings with Coordinating Center/Office leadership; and feedback given to project officers. Regardless of whether a project is funded, feedback is given to assist the applicant in seeking other funding or for re-proposing the project the following year.

To conclude, Dr. Zaza reviewed some of the challenges faced by COTPER. Coordinating the budget allocation process across the agency in a rigorous manner is very difficult. It is also challenging to maintain progress with decreasing funding. While the decreases appear to be small amounts, they are important to maintain ongoing operations and invest in new projects. Therefore, continuing to focus on making the best decisions is critically important. COTPER continues to have increasing mission and external requirements placed upon it that impinge on the shrinking resource base. Developing and evaluating projects that come from other coordinating centers/offices is also challenging, as it requires COTPER to exert leadership without authority over CDC-wide activities. Thus, COTPER is constantly working to help CDC staff improve how they propose and implement their projects. Moreover, it is difficult to improve the visibility of preparedness projects not funded by COTPER. Therefore, it is not clear how to tie that work in, track it, and make sure COTPER is not supporting efforts that are already being paid for in a different way.

Discussion:

Dr. Koh wondered whether the end result of the internal priority-setting process differed each year.

Dr. Zaza responded that part of the reason for the shift between 2007 and 2008 was due to new priorities from external sources (e.g., Homeland Security Presidential Directive 21). It is a challenge to balance external priorities or mandates with internally identified priorities. The hope is that as COTPER becomes better at this, we will observe fairly dramatic shifts in priorities and resources to areas of importance for the short- and long-term.

Dr. Ursano requested clarification regarding whether the \$260 million budget managed by COTPER included extramural funding outside of CDC, and if so, what percentage was intramural versus extramural.

Dr. Zaza replied that the \$260 million budget does not include the majority of extramural funding (e.g., 91% that goes out through the cooperative agreement program to states, and various other extramural programs such as Centers for Public Health Preparedness or BioSense funding). She was not positive what the precise percentages were for intramural versus extramural funds for the \$260 million. COTPER is attempting to better determine these percentages through their accounting systems, but certainly a substantial percentage is allocated to extramural funding.

Dr. Harrauld pointed out that two of the nine goals listed were in the critical area of communicating with the public; however, it was not clear how these fit with the five objectives and whether they were carried through in any way.

Dr. Zaza responded that this question was raised frequently. Communication is clearly one of the most important capabilities in public health preparedness, and COTPER does highlight communication in each functional area. There is functional communication and there is communication as an intervention. As communication and marketing interventions become an increasingly greater part of CDC's overall portfolio of activities, they are being captured functionally within the five functional objective areas. The two major areas where that occur are when communication is an intervention and when it is a risk communication activity during a crisis. These two major areas do not, however, obviate the use of communication elsewhere. Communication is crosscutting, and it is difficult to categorize no matter what the organizing framework.

With regard to preparedness funding by Coordinating Center/Office, Professor Hoffman wondered why there was a substantial reduction of about \$24 million between fiscal year 2007 and 2008.

Dr. Zaza responded that the reduction from 2007 to 2008 involved funds being moved out of upgrading state and local capacity in the grant in order to fund infrastructure needed to manage the grant. During 2007, there was a joint resolution for the entire year, so some funds were shifted within the organization.

In an attempt to sort out roles and responsibilities and to understand how COTPER has enough staff to carry out their work, Dr. Hamburg wondered if others were involved. She also wondered if COTPER could simply allocate their funding in accordance with their strategic plan rather than going through the competitive process.

Dr. Zaza replied that one of the challenges was that they were attempting to impose a strategic process on a historical budget. The CDC preparedness budget was formed out of existing budgets the agency already had, with an additional infusion of new funds. Other items were absorbed into this budget as well. For example, the vast majority of the quarantine budget for CDC is now within the preparedness budget.

Much of what COTPER does is allocate funds for on-going activities. However, COTPER has stewardship of the entire CDC preparedness budget, so COTPER is perceived as being entirely accountable for how the funds are used. COTPER has streamlined the budget allocation process, making the review process non-competitive for on-going operational efforts.

COTPER leads the strategic planning process for preparedness on behalf of the agency. Three goal team leaders for preparedness, representing COTPER, CCID, and CCEHIP, focus on different areas (all-hazards, infectious threats, and environmental threats). A team of people from across the agency volunteer their time to develop the strategy. Thus, allocation of funding is based partly on ensuring that COTPER is carrying out on-going activities that need to occur, as well as ensuring that there is an appropriate budget to engage in some new and innovative efforts that will move public health preparedness forward. It is a balancing act, but COTPER is continuously trying to streamline and improve the process so that it is sustainable.

Dr. Ursano thought that part of the challenge probably related to management of the issues pertaining to funding outside of COTPER. He wondered whether this would fall under the purview of the COTPER BSC, the BSCs for each coordinating center, or both.

Dr. Zaza responded that the COTPER BSC is the only board COTPER has, so the COTPER BSC would be called upon to review efforts specific to COTPER. The other coordinating centers have their own boards, three of which have already conducted focused reviews on their preparedness-funded work. However, these reviews do not preclude the COTPER BSC reviewing some aspects of preparedness programs at other centers, such as programs that cut across multiple coordinating centers. For example, biosurveillance activities cut across the entire agency, and some of the laboratory work is balanced across two major coordinating centers.

Captain Jim Terbush inquired as to where in COTPER's programs the individual and family preparedness and building resiliency goals were that were noted in HSPD-21.

Dr. Zaza replied that COTPER has initiated work within the preparedness goal action plan around vulnerable populations specifically. Much of this appears in public health systems support because the action is actually through the grants to a large extent. CDC typically does not have a close working relationship with the general public because the agency works by law and by authority through the state and local public health departments. Some of the work is in the public health system support objective area to ensure that the efforts made by the agency translate to populations and communities through those programs. In addition, there is not a lot of knowledge base in this area, so CDC has developed some strategies and priorities within epidemiology and other assessment sciences to try to better understand some of the risk factors. What are some of the population dynamics? What do we know about these populations? What are the issues? What are the needs? And, how are we going to address them? These would fall under targeted communication interventions, and potentially some work that the SNS group is interested in with respect to specific stockpiles and particular populations. In the Goal Action Plan, there is a specific annex for vulnerable populations, using the definitions of "at risk" populations that were developed through the PAHPA work and on-going work through HSPD-21.

Dr. Besser added that in terms of individual preparedness, while COTPER provides support across the agency and to state and local public health departments, DHS is the lead for individual preparedness. CDC is considering whether it should be doing more in the area of individual preparedness, and certainly wants to do more in terms of community resilience. COTPER has recently funded a new position to coordinate issues pertaining to emergency preparedness for vulnerable populations across CDC.

Division of Emergency Operations (DEO)

Mr. Philip Navin

**Director, Division of Emergency Operations
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention**

Mr. Navin indicated that while he did not have a public health background, he was a retired Army Colonel, Medical Service Corps Officer. From that Medical Service Corps Officer perspective, he introduced to CDC some of the techniques, tactics, procedures, and processes that have proven to work for the Army. In addition, CDC has a great deal of federal guidance that helps direct what the agency does and how it is done. One concept that has been introduced to CDC is bringing individuals together on a regular basis to provide updates to Dr. Gerberding with facts, assumptions, courses of action, and recommendations for decisions. It remains challenging to get everyone across the agency to understand the process, even though the military and others have used this process for many years. A very important effort was to help CDC understand the importance of exercising in order to become better at the processes, procedures, and tactics necessary to fulfill the agency's roles and responsibilities in the preparedness and response arena. Applying the principles of command and control, the Incident Management System (IMS), and the Incident Command System (ICS) on a daily basis has tremendously benefited the agency in terms of how it does business and the ability to respond quickly when a situation develops (e.g., hurricane, anthrax, etc.).

There are a number of COTPER BSC engagement opportunities that Mr. Navin suggested the members take into consideration as they listened to his briefing, including the following:

- Operations
 - Virtual Director's Emergency Operations Center (DEOC) operational capabilities
 - National Incident Management System compliance
 - Personnel Deployment Resourcing
- Logistics
 - Stocking deployment items
 - Inventory management process
 - Requirements
- Plans
 - Art of developing response plans
 - Plans clearance process
 - Exercise strategies/participation

DEO's vision statement is to be recognized as the premier national public health emergency operations center. With respect to its mission statement, DEO prepares CDC and coordinates responses. The division director's intent is to use the principles of the IMS to manage CDC resources to support public health activities, events, and exercises in coordination with internal and external partners by assisting with the deployment of assets, gathering and disseminating information, and coordinating and managing the activities / events.

Mr. Navin explained that the DEO had existed as an organizational structure for only about five and a half years. DEO was originally embedded with about five contractors in the National Pharmaceutical Stockpile (NPS), but was a sub-organization within the NPS. DEO was

separated from the NPS in 2005 at about the same time that COTPER was being established. Numerous other changes were occurring across the entire federal government as well, which also influenced DEO's organizational structure, mission, and design. DEO's mission-essential tasks are to serve as the 24/7/365 single point of information entry concerning public health threats and events; maintain situational awareness and alert CDC leadership and HHS; analyze, synthesize, and summarize all operationally relevant information for incidents; coordinate incident management training and staffing; establish and maintain effective communications and coordination with partners; develop plans and exercises for the 15 National Planning Scenarios; and provide logistical support. DEO personnel in collaboration with ATSDR, monitor CDC operations 24 hours a day. DEO has a contract with Innovative Emergency Management that provides telephone watch staff and information planning to include gathering and assembling daily summaries and briefings. One person is currently on board that monitors and produces medical threat information. During a response, the DEO will initiate surge actions such as additional telephone watch, duty officers, and administrative support personnel. Some key questions that COTPER BSC might assist the DEO in answering include: Is NIMS / ICS appropriate for public health? How do we design and incorporate exercises into the CDC / public health structure?

Some of the events for which the DEOC has been activated include the following:



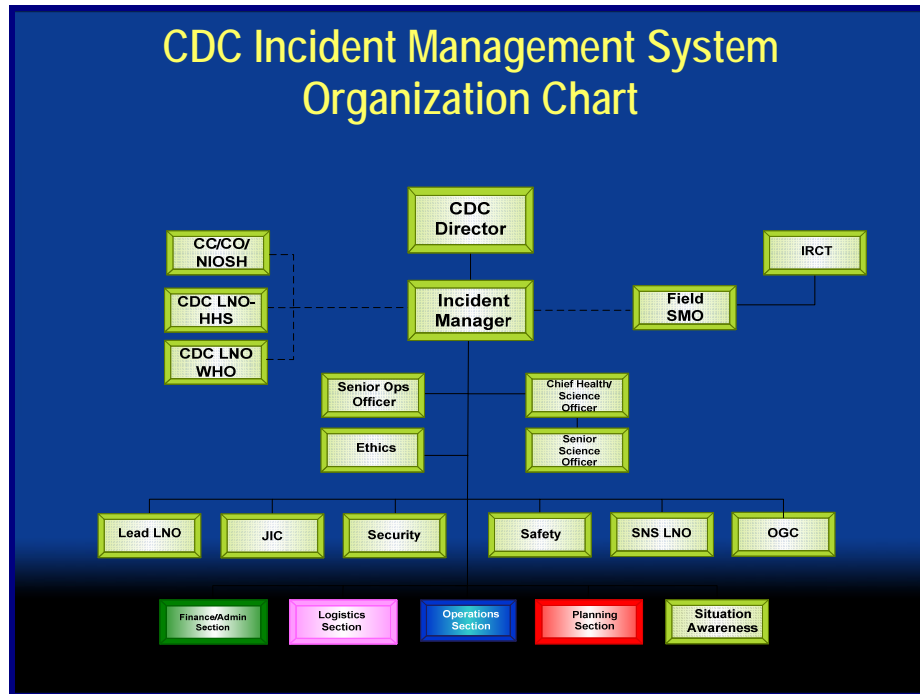
Mr. Navin reminded everyone that in 2001, there was not an official DEOC. An emergency operations center at that time consisted of a computer, telephones, tables, and chairs placed in the auditorium. It was not until after Hurricane Katrina in 2005 that serious consideration was given to how emergency management should be organized across CDC within an emergency management structure in a collective format. There have been numerous accomplishments since 2001. DEO has supported over 38 responses from September 2001 to September 2007. The DEOC was activated 166 days in 2007 and has been activated 45 days in 2008. From October 2005 to June 2008 the DEOC has triaged 73,113 events. Material support has been provided to over 1,000 CDC deployed personnel. DEO has coordinated 33 shipments and 24/7

deployment support for 18 public health events and 88 personnel, and supported over 1,000 participants during the January, April, and August 2007 Pandemic Influenza Exercises. In addition, DEO developed the Preparedness Workforce Management System (PWMS); has conducted 512 DEOC tours from October 2005 to August 2008; coordinated multiple responses to low level events; and standardized Do Not Board / Do Not Fly protocols. Mr. Navin highlighted the PWMS system, pointing out that the previous system was unable to identify specific skill sets, while PWMS allows one to drill down to very detailed information about personnel (e.g., security clearance, passport, specialties, skill sets, etc.). This enables better personnel matches to meet the mission requirements for an event.

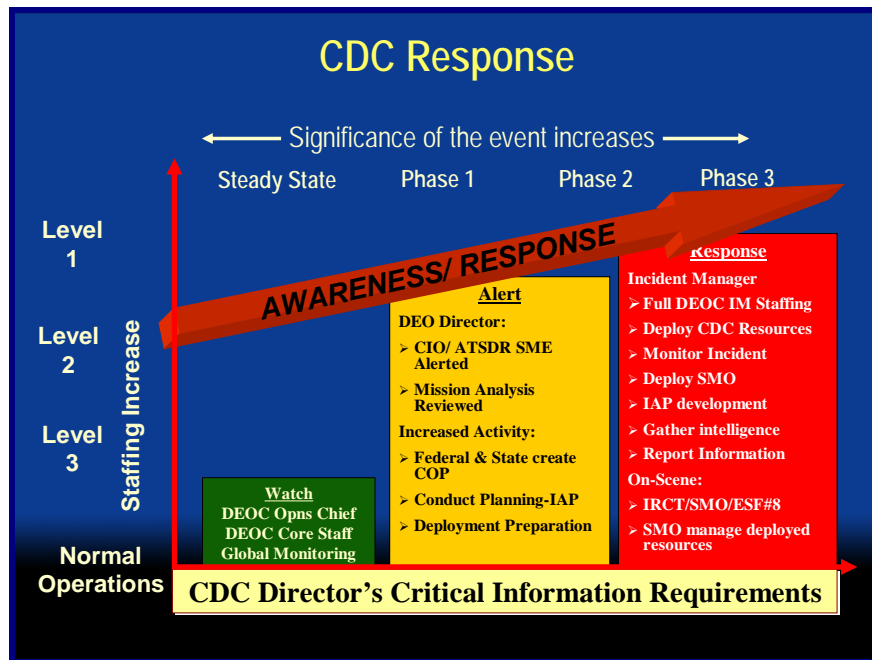
Using an ICS framework, DEO is organized with three permanently staffed teams: Operations, Logistics, and Plans. The Operations Team manages the emergency operations center 24/7/365, including triaging phone calls and providing audio-visual and administrative services to support over 200 staff if necessary. This team also maintains situational awareness and keeps CDC leadership and HHS informed through CDC daily reports, Health Alert Network (HAN), and Situation Reports. The Operations Team is also responsible for rapid analysis of limited information with CDC leaders and subject matter experts to confirm / deny an event; for conducting safety and wellness checks of CDC staff in an area impacted by a disaster; and for establishing and maintaining effective communications and coordination with numerous internal and external partners.

The Logistics Team manages property accountability for the DEO and provides logistics planning support during emergency responses to include: continuity of operation (COOP) events; procures and manages supplies in response to emergency deployment operations and COOP events; coordinates CDC deployment equipment and personnel transportation; coordinates and tracks specimen, supply, and equipment shipments; and coordinates all CDC medical evacuation missions with CDC Office of Health and Safety (OHS). Should something happen at the main CDC campus, there are two other COOP sites in Atlanta, one to the north and one to the south. Given the likelihood that there may not be infrastructure to support personnel in an event setting, logistics must be provided for as personnel are deployed. Using FEMA, fire service, and military models, the Logistics Team provides a centralized location for all event requirements such as travel orders; equipment; automobiles; meals ready-to-eat (MREs); backpacks; tents; sleeping bags; communications equipment; etc.

The Plans Team develops, coordinates, and disseminates response plans. In addition, they train CDC / DEOC staff on current CDC response methods and procedures. They also develop, execute, and evaluate CDC exercises to measure the effectiveness of plans. The Plans Team is also responsible for coordinating with other federal agencies to support and synchronize response planning; integrating science into planning to ensure responses are scientifically based; and developing Incident Action Plans. The nesting of plans is important to understand. DHS is in the process of developing very broad strategic guidance statements to reflect what is occurring across the entire planning system that eventually results in concept plans, operational plans, tactical plans, and other areas depending on where one is in the organizational structure. When activated, the DEO organizational chart is as follows:



Since Hurricane Katrina, CDC has been introduced to the basic principles of incident management systems (IMS) (e.g., continuity, stability, consistency, familiarity, day-to-day, scalable, and transparent transition to event). In addition, the management and reporting structure have been simplified and there is functional alignment versus organizational alignment. DEO has stabilized each of the functional seats within the DEOC. While particular functions may not be needed during an event, there is a permanent seat, with a permanent phone number and permanent e-mail address that can be used when necessary. It does not matter who sits in the chair to represent a particular function; that is, phone calls are made to that functional representative, not a particular person. Personnel are on-call in order to be able to respond to the various functional desks within the DEOC. There are three staffing levels: Level 3 is minimal staffing, Level 2 is increased staffing, and Level 1 is maximum staffing. There are 232 Action Officer seats in the EOC, which is approximately the size of other similar emergency operations centers such as North American Aerospace Defense Command (NORAD) and U.S. Northern Command (USNORTHCOM). The level of significance may differ based upon the incident. If a town is destroyed by a tornado, their level of significance is going to be very high (Phase 3) because they no longer have the infrastructure. However, the NOC, NORAD, NORTHCOM, CDC, and / or HHS may still be at a steady state or a Phase 1. The significance phase will depend upon the responsibilities of the particularly agencies associated with an event. The CDC response is illustrated as follows:



All emergency command centers have criteria for notification. The CDC has the Director's Critical Information Requirements (DCIR). CDC's DCIRs which include:

- Disease outbreaks / deaths that are above the base line for the seasonal or geographic norm
- Department of Health or physician inquires of suspected H5N1
- Confirmed bird / animal H5N1
- Any chemical, biological, nuclear threats or events-airborne releases, natural hazard or water
- Media interest for any accidental or intentional agent or toxin release / use
- Vaccine adverse affects resulting in death
- Food-borne illness resulting in above base line numbers
- Accidental death / injury of CDC personnel
- Requests for use of CDC aircraft
- Requests for SNS assets
- Events affecting CDC installation activities / operations

These are very broad and probably require a great deal of interpretation, but are enough to raise the Steady State to a Phase 1, 2, or 3. Some of the DCIRs may require Mr. Navin to awaken Dr. Besser and / or Dr. Gerberding in the middle of the night, depending upon the significance of the critical information requirement being met. DCIRs become more detailed and change constantly once an event occurs. There is a continuous exchange of information once an alert is received that an event may be occurring. This is certainly not done in isolation. The DEOC has numerous major partners and stakeholders within and outside CDC, the latter including state and federal partners. Partner organizations and staff continue to grow over time. When the DEOC began in 2002 - 2003, it had a few contractors. Eventually, the division has gained a number of government employee authorizations for Full Time Equivalents (FTEs), and its budget has remained in a fairly steady state.

The DEOC's major challenges include recruiting personnel; acceptance of incident management practices for emergency response activities; Subject Matter Expert (SME) information collaboration and synchronization through DCIRs; exercise development, funding, and participation; balancing response activities for simultaneous events; release authority for use of CDC aircraft in time sensitive situations; lengthy travel voucher payments process for deployed personnel; availability of funding for upgrading deployment laptop equipment and DEOC desktop computers, which must be done approximately every two to three years; and authority to use appropriated funds to acquire and issue CDC uniform clothing items for deployment.

In conclusion, Mr. Navin reflected again upon the potential engagement opportunities outlined earlier for the COTPER BSC with respect to the DEO / DEOC.

Discussion:

Captain Terbush pointed out that emergency operations centers look increasingly similar in design, but are not interchangeable. With that in mind, he wondered how the time between detection and the ability to make a decision could be reduced.

Mr. Navin responded that he and Dr. Besser have discussed this with Dr. Gerberding. Being able to recognize that there is a problem is the first issue. This requires having in place the correct subject matter experts, people who have the authority and responsibility to make decisions, and understanding that the basic fundamentals of decision making are critical. The DEO spends a lot of time and effort teaching these concepts during exercises. Separate classes and courses are also offered outside of exercises in order to expand the knowledge base regarding how to detect and make decisions. It remains a challenge to get the larger population across CDC to understand this.

Dr. Koh requested additional information regarding the criteria for triggering activation of the DEOC and who makes the ultimate call to activate it.

Mr. Navin responded that this depended upon the situation. For example, recognizing that Tropical Storm Edouard had the potential to become a hurricane and not knowing what category it might be, he would request pre-landfall approval from Dr. Besser to activate to Level 3 status with minimal staffing. Dr. Besser would subsequently make this request to Dr. Gerberding. Once the request began working its way through, Mr. Navin would work with the various centers, institutes, and organizations throughout CDC to inform them of the activation status and to seek the skill sets they would need to bring into the DEOC based on a tropical storm Category 1, 2, or 3. This process is initiated rapidly with a simple phone call or email to Dr. Besser and a rapid response from Dr. Gerberding. Activation may also be influenced by media attention, potential geographic involvement, number of impacted states, potential number of deaths, etc. While multiple triggers may influence whether to go to an activation status, the decision process is extremely quick.

Dr. Arnold inquired as to whether there were internal plans for COOP within Mr. Navin's own functional group, and whether there was any cross-training between other portions of the agency in order to bring other CDC or external personnel in if needed as back-up. For example, during a pandemic in which multiple regions in the country are affected, the agency may need to rely on other resources.

Mr. Navin replied that this question frequently arises in terms of whether resources and systems are in place to allow additional personnel to be brought in when needed, such as those who are retired who have the requisite skills and capabilities. The DEO is working to ensure that OPM and OMB have those processes in place, and with CDC to ensure that processes are in place within the agency, in order to bring in additional people for surge capability when needed.

Dr. Harrald wondered what situational awareness looked like in practice, particularly in terms of the DEOC interacting closely with the FEMA National Coordination Center, the Secretary's Emergency Operation Center, and DHS's National Operation Center. Each of these centers is trying to maintain situational awareness, which ideally should be the same situational awareness, but seldom is. He wondered if at least it was possible to know whether they were looking at different situations.

Mr. Navin responded that this is an on-going issue. DHS has a site called Homeland Security Information Network (HSIN) that is supposed to provide a common operating picture through collaboration. However, a common operating picture of situational awareness is simply not possible yet. The BioPHusion center is bringing information together in such a way that one does not have to review twelve sets of slides or twelve pdf documents in order to figure out what is needed. The organizational structure within COTPER and CDC allows them to know when they are looking at different situations. CDC has made tremendous improvements in being able to recognize that, and it is a continuous effort.

In terms of reporting information, Dr. Mary Mazanec noted that CDC was obviously going to be the portal for a great deal of information coming in from state partners. She wondered whether any criteria or triggers were in place, given that they were probably wading through a tremendous amount of information before determining when to send it up to the Secretary's Operation Center, the NOC, or the other operations centers. That is, when is an event reportable via the pathways that are set up?

Mr. Navin responded that with states, they must rapidly establish a cut-off time for case counts (for salmonella, for example) in order to collate and validate them so they can subsequently be submitted to the Secretary's Operations Center. The data is sent to the National Operations Center, which forwards them to White House. The cut-off time may also be based upon the need to have data in time for a press conference.

Dr. Besser added that CDC places a great deal of effort on improving information sharing and flow, but this is still far from where it needs to be. Part of the problem is due to dealing with a very entrepreneurial culture. For example, he spent most of his career in the Infectious Disease Center where he was the head of the Legionnaire's Disease Program. If he received a call from a hospital that indicated that there was a Legionnaire's disease outbreak, his group would handle that. There was little incentive for him to share that information elsewhere. As an organization, CDC is engaged in extensive efforts to educate personnel within the agency about why some information people believe would be most appropriately contained within a small organizational part of CDC should actually be shared, what other groups could contribute, and why as part of the federal government there is a responsibility to share information in a safe way within the agency. There are concerns about interfering with the relationship CDC has with state and local public health if they share certain information. There are concerns within the wider organization of losing autonomy, losing control over the response as COTPER gets involved. Therefore, COTPER is working to develop trust within the agency while working to provide a service to the rest of the government by keeping them informed.

Dr. Terry Adirim wondered how helpful it was to have representative from each agency at the various operations centers.

Mr. Navin responded that CDC has numerous liaison desks in the DEOC (e.g., DoD, FBI, HHS, DHS, EPA). Their intent conceptually is to have liaison linkage. During the anthrax exercise, a CDC representative was placed in the Strategic Information Operations Center with the FBI, so that while the FBI was investigating the case, a CDC connection with the FBI was already in place.

Dr. Arnold inquired as to whether CDC planned to address cyber terrorism with respect to whether potential acts of terrorism may interrupt information flows.

Mr. Navin responded that this is a scenario under consideration.

Dr. Harrald wondered how, as the DEOC activation rate went up and expertise was drawn from across the agency, daily operations would continue throughout the agency. He pointed out that one avenue is a virtual operations center. Some staff may not be needed full time. They could be at their desk doing their day job and pulled in virtually when needed.

Mr. Navin agreed that over time, agency capacity in on-going programs could potentially be diluted. Decisions would have to be made by organizational leadership pertaining to whether to continue HIV and / or other on-going programs throughout CDC if all of the agency's attention needed to be devoted to a hurricane response, for example. Plans are set forth in the COOP; however, all decisions cannot be made ahead of time. This is situationally-dependent. He agreed that a virtual operation was one option.

Dr. Sosin stressed that while there remains a lot of work to be done in terms of reaching a common operating picture and situation awareness, a great deal of progress had been made with respect to information sharing systems, GIS, etc.. The federal government has made considerable investments, and DHS is making significant efforts to share those investments for the use of a common platform for a common operating picture. The assignment of staff is not just during a standup of the operations center. The DHS National Biosurveillance Integration Center (NBIC) is attempting to get all of the departments and agencies to place real time personnel on the ground there. While these personnel cannot be the most experienced person from each department or agency, this effort is creating an important link on a daily basis. The CDC person who is with NBIC is helping to triage, to be the focal point into the DEOC, and the link throughout the agency. This is a formative neural network that is becoming better trained and more expert in making human connections and in the electronic sharing of information through common platforms.

Dr. Adirim clarified that the National Biosurveillance Integration System (NBIS) is supposed to supply the biological common operating picture, and the NOC is supposed to facilitate a common operating picture. She thought both systems benefited from having liaisons from various agencies.

Dr. Koh inquired as to whether, as they were going through national exercise programs with all of the emergency operations centers, the time to endpoint was being tracked in terms of making coordinated decisions that are released to the public.

Mr. Navin responded that they were. A priority of Drs. Besser and Gerberding is being able to measure response time for bringing information in and sharing that information with leadership, the state, etc.

Dr. Besser added that at this point, measuring response time is largely aspirational. CDC plans to conduct a couple of pilot activities within DEOC that will examine fairly common scenarios to determine how long it takes to connect to the appropriate expert within the agency to respond back to calls from the public. Being able to measure during real events how the agency is responding is critical to continuing improvement within the DEOC. This might be an area of interest to the COTPER BSC.

Division of Strategic National Stockpile (DSNS)

Mr. Greg Burel

Director, Division of Strategic National Stockpile

Coordinating Office for Terrorism Preparedness and Emergency Response

Mr. Burel began his presentation by posing the question: Whose picture of the Strategic National Stockpile (SNS) would be similar to the endpoint in *Raiders of the Lost Ark* where there is a big dusty place where stuff goes in and gets lost? With that in mind, he stressed that he wanted to impress upon everyone that there is much more to the SNS than simply storage of [materiel](#). While storage is vitally important, other efforts must be made to ensure that what is stored is useful.

The mission of the Division of Strategic National Stockpile (DSNS) is to deliver critical medical assets to the site of a national emergency. DSNS does this by working within the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) requirements process to assure that they have the most appropriate countermeasures. DSNS creates pathways to move the materiel to the area of need in the timeframe that is clinically relevant. Given that medical response is local, DSNS assures integration with local planning, provides technical assistance to assure that state and local partners who receive SNS assets are ready to effectively use them, and scores states' plans to ensure that they can be operationalized should the need arise. DSNS also maintains materiel in a manner that assures viability.

To fully understand DSNS's roles and responsibilities, Mr. Burel first introduced some other concepts before getting too deeply into the SNS: BioShield and Biomedical Advanced Research and Development Authority BARDA. He explained that BioShield was legislation that created funding for "next generation" countermeasures. The goals of Project BioShield were to strengthen NIH development capabilities; give FDA the ability to make promising treatments available quickly in emergency situations; and store new BioShield-funded products in the SNS. No money has been appropriated for storage, maintenance, and replacement of BioShield-funded products although this does impact SNS planning and costs. Additional information about BioShield can be found at <http://www.whitehouse.gov/infocus/bioshield/>.

The Biomedical Advanced Research and Development Authority (BARDA) is an office under the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. BARDA manages Project BioShield and among its many other responsibilities is tasked with procurement and advanced development of medical countermeasures for chemical, biological, radiological and nuclear agents, as well as pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield. Given that much of their work directly impacts the SNS, the DSNS “holds hands” with BARDA in order to ensure that everything works correctly.

Turning to the SNS, Mr. Burel reported that this program was created in 1999 and was originally known as the National Pharmaceutical Stockpile (NPS). The DSNS currently holds a \$3.5 billion portfolio of antibiotics, medical supplies, antidotes, antitoxins, antiviral, vaccines, and other pharmaceuticals. The SNS is stored in a network of strategically located repositories, the precise location of which is closely guarded for security purposes. Commercial partnerships are used for the storage, transportation, and maintenance of these materiel and the DSNS relies upon federal partnerships for purchasing and security. In addition to some of the purchasing work being done at BARDA and CDC, DSNS also leverages the capability of the Veterans Administration (VA) National Acquisition Center to purchase assets. The VA is responsible for the federal supply schedules for medical materiel of various types, so they are often able to negotiate more rapidly and get a better price on large purchases of the medical materiel made on CDC’s behalf. For security, partnerships are in place with the U.S. Marshal Service. Approximately 36 U.S. Marshals are assigned to the stockpile to assist with security for the materiel as it stands in place and as it moves when deployed. The SNS formulary continues to evolve. DSNS plans to supplement and re-supply state and local medical materiel response, given that in most cases, states are not going to have the materiel that the SNS holds. DSNS provides extensive training and technical assistance to local officials, and tries to integrate into the broader national public health preparedness effort.

In terms of the budget, in 1999 the DSNS had very few federal employees and contractors authorized. Currently, the division’s total authorized staffing for federal and contract employees exceeds 250. Many staff members are not in place currently, and DSNS is very careful to stay within a reasonable number of the authorized pattern. This offers them the ability to address surge capacity, and then staffing can be backed down as necessary. The budget line was less than \$50 million for the first few years of the program. Not surprisingly, it spiked in 2002 and dropped somewhat in 2003. Some of the 2002 funds were provided for pandemic influenza. There has been slow growth in funding since 2003, with the DSNS’s budget at just under \$600 million for 2008.

The formulary is based primarily on Bioterrorism Category A Threat Agents: Biological (e.g., smallpox, anthrax, botulism, viral hemorrhagic fevers, plague, and tularemia); Chemical (e.g., nerve agents), and Radiological. Threat assessments (Material Threat Determinations) are made by DHS, which leads the PHEMCE to make recommendations about what needs to be purchased to go into the stockpile to address those threats. DSNS carefully considers placing the recommended assets into the stockpile based upon whether they are readily available in the commercial marketplace, and whether they can they be produced in a rapid manner if they are needed to respond to an event. Because the commercial drug marketplace truly operates in a “just in time” fashion, there is little extra supply for rapid acquisition. For non-bioterrorism events, DSNS also holds the nation’s supply of pandemic influenza antivirals, which are

designed under contract to be used if there is pandemic influenza. They are not to be used for seasonal flu.

There was a time when the SNS formulary process was not quite so concrete or as well-formulated. The PHEMCE has brought some shape to the way the DSNS makes decisions about what is included in the formulary. The PHEMCE is an interagency effort that is coordinated by ASPR, and includes the three primary HHS internal agencies: CDC, FDA, and NIH. The PHEMCE mission is to define and prioritize requirements for public health emergency medical countermeasures; integrate and coordinate research, early- and late-stage product development, and procurement activities addressing the requirements; and set deployment and use strategies for medical countermeasures held in the SNS. The PHEMCE considers medical countermeasures to address chemical, biological, radiological and nuclear threats; as well as naturally emerging infectious diseases and pandemic threats, including pandemic influenza. Hence, anything placed into the formulary has been vetted by integrated program teams that are part of the countermeasures enterprise. Their recommendations are submitted to an Enterprise Executive Committee that makes a final recommendation to the Enterprise Governance Board. The Governance Board is comprised of Dr. Gerberding and others who review the recommendations. The PHEMCE must explain and defend why particular decisions have been reached and why certain recommendations have been made. A final decision is then made about procurements.

DSNS's emergency response concept includes three components: rapid delivery of a broad spectrum of support for an ill-defined threat in the early hours of an event; specific materiel when a threat is known; and technical assistance to states to receive and effectively distribute SNS materiel. DSNS provides threat-appropriate delivery mechanisms, which vary based on the event. There are several operational approaches depending upon the type of event: CHEMPACKs (forward placed caches); 12-hour Push Packages (which represent about 3% of DSNS's total holdings); Managed Inventory of Vaccines and Antivirals (SNS managed and vendor managed) and other medical materiel; and Direct Order Prime Vendor Contracts.

CHEMPACK is a nationwide joint venture program for forward placement of nerve agent antidotes. The DSNS enters into memoranda of understanding (MOUs) with states to allow the forward placement of these caches. The DSNS recognizes that nerve agent antidotes have no utility unless they are administered almost immediately, so they are placed where they might be needed. There are two types of containerized storage for CHEMPACKs. The formulary is uniform across the two, but the packaging is different. There is a hospital container, which contains primarily bulk-packaged chemical nerve agent antidotes that must be used by persons who can break down the bulk product and administer it. There are also EMS containers that are placed forward so that EMS personnel can use auto-injectors. A great deal of work went into the design of the containers to enable just one person to grab and move them through a standard sized doorway, which is critical if response is to be as rapid as possible. This would be of little benefit if it required a forklift, 15 people, and a special door. There are currently about 2,000 CHEMPACKs in place across the United States. DSNS estimates that over 50% of the population lives within one hour of a CHEMPACK placement.

The 12-hour Push Package is what DSNS is primarily known for. This is a 50-ton package of materiel that is of broad spectrum. It includes antibiotics of different types and other materiel to address a broad spectrum of possibilities. There are currently bottles of antibiotics (300,000 units of use) for people who might be exposed to anthrax. Again, the containers are designed to make maximum use of a wide-bodied aircraft. This load fills a 747 airplane or 8 to 10 trucks. It is designed to take maximum advantage of the fuselage's capability to hold materiel, and weight is

distributed in such a way that the plane can take off and land without additional runway space or having a fueling issue. Pre-packed and configured materiel are in transport-ready containers and are pre-positioned in secure facilities located near major transportation hubs. The plan is to rely primarily on movement of these containers by air, but they could also be moved in a number of multi-modal scenarios. They are delivered rapidly by world-class transport partners with whom CDC contracts. The contract terms and conditions are such that from the time the contractor picks up the Push Package to the time they hand it off to a state must be 12 hours or less. In the most recent exercise, the Push Package was delivered within 10 hours. The materiel are placed in the containers, which are color coded and numbered so that state and local authorities can quickly look at these, know exactly what is in them, break them down, and move materiel rapidly.

The DSNS's managed inventory includes Stockpile Managed Inventory (SMI) and vendor-managed inventory (VMI). CDC does not own or lease warehouses. Instead, the agency enters into Third Party Logistics (3PL) contracts with private sector entities that know how to manage warehousing and movement of materiel. CDC does not own forklifts or pallet jacks and does not have to ensure that people have forklift operator licenses, etc. Instead, the agency relies on leveraging the private sector to help manage these materials. In addition to the inventory maintained in a 3PL warehouse, the contracted entity is required to maintain a separate independent inventory of that materiel. The 3PL warehouses are approximately the size of two Super Wal-Marts racked floor to ceiling. The VMI is somewhat different, and has been described as supply "bubbles" or "virtual stockpiles." For VMI, CDC will obtain an option to buy if there is a need for particular items. The vendor must then always have available to CDC the capability to deliver, at any time, units of whatever is needed. Or CDC will purchase the materiel that the vendor holds for the agency physically, but they will rotate it into their commercial marketplace and replace it with newer stock so that stock is not constantly expiring and having to be re-purchased. Over the last several years, CDC has had to write off only about \$40,000 against a \$3.5 billion total inventory value.

The DSNS believes that its technical assistance for countermeasure dispensing efforts is one of the most important things the Division does. If CDC has not created the capability within state and local partners to distribute and dispense these materials after it is handed off to them, it will not matter (like the buses in Hurricane Katrina). Pre-event training is conducted currently based upon *Version 10.02: Receiving, Distributing and Dispensing Strategic National Stockpile Assets*. The Cities Readiness Initiative includes 72 cities / metropolitan statistical areas. The division provides technical assistance to the 62 project areas and conducts technical assistance reviews for all project areas at least annually unless the plans are scored at a level below a certain numeric cut-off, in which case they are done every six months until that score rises. The Division also offers state and local exercise support and evaluation, and offers classroom instruction. In 2007, the Division taught over 2,000 persons how to receive, stage, store and move this materiel. Satellite educational broadcasts are also conducted (10 have been done and 2 are planned) to assist state and local partners in understanding how to dispense the materiel. The division is working with a pilot program for SNS field staff, which will ultimately integrate with COTPER in Communities, and is an important support aspect to put people in the field to help those states having trouble understanding what to do with the materiel. Post-event, the DSNS can deploy a Technical Advisory Response Unit to a state in a rapid timeframe via CDC's contracted aircraft. This Unit has been flown in during times when nothing else was flying, such as just after 9/11, so that staff could be on the ground before a Push Package or Managed Inventory arrived in order to help the state understand what to do with the materiel and to help them move it around.

The DSNS faces a number of challenges. An ever growing percentage of the SNS budget is consumed in storing, maintaining, and replacing the countermeasure inventory acquired with both SNS and Project BioShield funding. New BioShield-funded products will be stored in the SNS, but no funds are provided for storage, maintenance, or replacement. Lifecycle costs are a significant part of any acquisition. Countermeasures are of no value if they cannot be dispensed in an appropriate timeframe. State and local capability to effectively dispense is an on-going challenge. By 2014, the division estimates that its replacement cost could reach almost \$900 million, with more than half of that being related to the Project BioShield purchases for which no money has been provided for that replacement.

In conclusion, Mr. Burel shared how much he appreciated his involvement with the SNS, which was one of the greatest aspects of his career, and commended those who originated the program. He stressed that the DSNS was probably the most closely examined program in COTPER, and invited the COTPER BSC members to offer any input they could for improvements to the program.

Discussion:

Dr. Harrauld asked for further clarification about standards and whether states' capabilities and vulnerabilities are being assessed as part of that. For example, how many states use their National Guard as a critical part of the distribution system? He also wondered whether DSNS had given any consideration to tying in with the Emergency Management Accreditation Program (EMAP) states are going through.

Mr. Burel responded that there are specific standards states must meet, which are contained in the guidance known as *Version 10.02 Receiving, Distributing, Dispensing Strategic National Stockpile Assets*. Training classes are conducted with state and local responders to ensure that they understand this guidance before attempting to apply it. With respect to assessment of the states' plans, CDC worked with states and the Rand Corporation to develop a set of criteria for development and review of state plans. Substantive thought went into how to score various aspects of the plans, and the assessment is being continuously revised and improved over time. With regard to the National Guard, various states and localities have different plans to leverage different assets within their states. Some do have plans to rely on their Guard if the Guard is available, but most also have back-up plans to rely on others if necessary. States are using a variety of approaches. While DSNS does not direct states on how to plan their approaches, they can offer advice about whether the plans will work based upon the criteria that are scored. While DSNS has not considered EMAP with respect to the SNS, it is valid to consider.

Dr. Besser added that in terms of measuring capability CDC is assessing plans, which is very different. He requested that Mr. Burel expand on some of the efforts underway to develop drills and measure capabilities.

Mr. Burel replied that the DSNS is working with the Rand Corporation to establish drills and exercises that would measure capabilities based on exercising and working within the actual plans that have been developed. This will help to establish whether the plans are sound and can be operationalized. This is also a financial issue for states.

Speaking as a Local Health Officer, Dr. Smith commended CDC for this program. She thought it was one of the best programs, particularly with respect to the rollout, that CDC ever developed in terms of the balance between direction and flexibility. CDC provides adequate training to

state level staff, which is extremely important since states are variable in their capacity and turnover is high.

Mr. Burel expressed his appreciation for the praise, acknowledging DSNS's recognition that there is much more to do.

Professor Hoffman requested more details about how exactly DSNS measures the success and scores activities.

Mr. Burel replied that DSNS sends a consultant to evaluate the state's plans based on a pre-defined set of criteria. The state has those criteria in advance, so they are aware of what will be evaluated. While he did not have the precise criteria with him, Mr. Burel indicated that it would be provided to the members by the next day. The criteria were developed with the Rand Corporation, and state and local health departments to ensure that everyone agreed that the appropriate issues would be assessed. DSNS walks states through their plan during the evaluation, involving their local law enforcement and emergency management agencies, so that this is not just a public health-centric effort. DSNS encourages states to reach out to emergency management at the state and local levels. The US Marshals help DSNS create a bridge between public health and law enforcement to understand how everything fits together. When the plan is reviewed and scored, DSNS produces a draft that is reviewed by the state to determine whether anything has been missed and needs to be brought forward. Following the state's opportunity to provide additional input, DSNS produces a final score. States are aware in advance of what will be assessed, how they will be scored, and are permitted the opportunity to offer additional input before the final score is rendered.

Dr. Adirim suggested that this would be a good area in which to invest in systems research in order to determine the best ways to dispense the stockpile.

Mr. Burel responded that DSNS concentrates significantly on the issue of dispensing the stockpile, and has done a lot of work with the Institute of Medicine (IOM) recently to consider various dispensing methods. DSNS is always open to new ideas, and many interesting ones have been offered. However, one issue is that often the ideas cannot be operationalized. For example, it has been suggested that pharmacies could dispense the stockpile. However, pharmacies do not believe they can manage this responsibility because they do not have the staff or security to do so. Work is continually going on with respect to new and different modalities for dispensing. A possible focus for the COTPER BSC will be to consider whether there is an actual or perceived problem with respect to distribution and dispensing capabilities, and if there is an actual problem, how they might sort through some of the great suggestions that have been offered. Consideration is also being given to establishing an operations research capability within the SNS. This has been highly recommended, and DSNS believes it would be beneficial to examine systemic issues over time. They have also begun to try to include planners. They met recently with Rear Admiral Charlie Lilli, USNORTHCOM's Director for Logistics and Engineering, who offered for his logistics planners to assist DSNS in an interim phase.

Dr. Gary Raskob asked Mr. Burel to summarize some common observations of state or local health departments that have not scored well.

Mr. Burel responded that a consistent problem observed among those not scoring well is that they cannot demonstrate that they have a clear pathway to people who will engage in the labor-intensive process of dispensing countermeasures. DSNS is considering ways to mobilize federal assets that are in certain areas to try to bring to bear more volunteers. It is known that federal employees will often volunteer when others will not; however, that is not a solution in itself. Clearly, they must find other ways for countermeasure distribution/dispensing that are not as labor-intensive. Although having the U.S. Postal Service deliver house to house is a possibility, that is labor-intensive in a different way and other issues must be considered as well (e.g., security and safety).

Dr. Ursano wondered whether modeling was being done in terms of different distribution networks and hit rates for distribution.

Mr. Burel responded that DSNS is doing modeling in that area. They did modeling with the Logistics Management Institute at the outset to determine where to stage the materiel in order to be able to respond to various scenarios. DSNS continues to do modeling internally and externally with respect to advanced deployment of materiel; distribution; what to dispense; what dispensing sites look like based on current guidance; etc. This is an area that is ripe for additional work, and more research into this area is important.

Captain Terbush requested further information about the MedKit program as a possible solution to countermeasure distribution.

Dr. Besser replied that MedKit is a concept of home stockpiling of countermeasures. There are a number of approaches to countermeasure distribution, but home stockpiling has some level of appeal. If there is a time-sensitive exposure for which people had the countermeasure in their home, they could take it when indicated. The down side has to do with misuse and abuse driving antibiotic resistance. There are limited drugs that can treat common infections, let alone resistant infections. MedKit is a way of trying to approach this in a safe manner. A kit was developed for home stockpiling that looks like an emergency kit, with instructions about when and how it should be used. It is sealed in a clear plastic packet. This kit was tested a year ago in St. Louis in over 4,000 households; 13,000 individuals; and 3 different cohorts (e.g., first responders, a community clinic population and a business cohort). Over a period of up to 8 months, greater than 95% of the households had not used the kit and people felt better having it in their homes. This is moving forward on a path towards licensure, although a couple of additional studies must be conducted before it can be licensed. Once it is licensed, it could provide another way of approaching countermeasure distribution. There remain numerous operational issues that would still need to be worked out (e.g., cycling drugs that expire in a year, equity issues, etc.). It certainly is a potential modality that could improve resiliency and timeliness.

Mr. Stephens inquired as to the percentage of the budget that was allocated to storing and maintaining assets versus replacement. He also wondered if consideration had been given to centralized federal oversight of the assets through the General Services Administration (GSA), given that others outside of HHS have significant amounts of storage.

Bob Phillips responded that approximately 35% to 40% of DSNS's total annual appropriation is allocated to storage and replacement.

Mr. Burel added that storing for DSNS is more than just paying for the cost of keeping the assets in a place. The storage requirements for the medical materiel in the SNS are very stringent with respect to humidity and temperature control. The storage costs also involve managing and maintaining that inventory, replacement value, and other issues. With respect to the possibility of sharing space, based on his experience with GSA and FEMA, it was clear that storage space was dwindling rapidly. In addition, a great deal of that space would not be positioned where it would allow DSNS to handle the multiple distribution models they need to be able to run to deploy the SNS assets as rapidly as possible.

Dr. Arnold, a Medical Director for Illinois Department of Public Health, noted that a problem at the state level is that they have 95 local health departments, many of which are supported by practitioners who are given blanket authority for signatures for prescription authority based on the treatment of HIV or STDs. However, they do not want to be involved if there is a pandemic. About 60% to 70% of them are not actually paid by the clinics that they are supporting with signature authority. This raises the issue of who will sign for the assets once they have been distributed. He suggested to the FDA that at the time of an emergency, these pharmaceuticals could be made available for over-the-counter (OTC) acquisition. People go to Walgreen's to buy over the counter medications such as Ibuprofen or Advil.. At some point, it was decided that these items would be made OTC in order for people to treat themselves. This is a way to get around a lot of legal liability. Perhaps CDC could work with FDA to change the prescriptive authority. In addition, he wondered whether shelf-life extension issues needed to be taken into consideration from a legal and pharmacology standpoint.

Mr. Burel responded that DSNS manages shelf life very carefully. Those products that are not biologics can be entered into the Shelf-Life Extension Program, a joint program managed by the DoD and FDA which allows CDC to sample its products by lot as they near or reach expiration dates. The FDA can tell CDC whether that materiel can be relabeled for a longer shelf-life based on whether it passes testing for stability, integrity and potency. The other way DSNS handles shelf-life is that vendor-managed materiel can be rotated out into the vendor's commercial marketplace. DSNS is also working with the DoD regarding the anthrax vaccine, given that they use it very rapidly. CDC is currently working to deploy its anthrax vaccine to the DoD so that they can use it in a proper manner before its expiration. The DSNS will replace its supply with fresh anthrax vaccine. In terms of who can sign for and dispense the SNS, the antivirals are currently assigned to treatment and are not for prophylaxis. The way stockpiled antivirals are distributed and dispensed will be dealt with very differently than how some other medical countermeasures would be dealt with (e.g., prophylaxis for anthrax).

Dr. Koh pointed out that despite all of the incredible advances, one of the challenges of this kind of work is that the public does not see the extraordinary progress that has been made because these assets are not deployed unless there is an event. He wondered if there were ways in which DSNS could demonstrate its capabilities to the every day world on a more frequent basis.

Mr. Burel stressed that preparedness is not cheap, and it is difficult to justify purchasing and maintaining stockpile assets that they never really want to have to use. Throughout COTPER, from a preparedness program perspective, it is extremely difficult to garner funding when it appears that nothing is resulting from it. It would be of great benefit if the COTPER BSC could offer insight into ways these capabilities and accomplishments can be illustrated, particularly as funds continue to dwindle and increasing funds are required to maintain and expand the capabilities that have been developed. However, a major challenge is that caution must be taken with regard to the information released about the SNS in order to avoid inadvertently informing the enemy.

Day 1 Closing Remarks / Adjourn

Dr. Sosin reminded everyone that there was an optional DEOC tour following the close of the COTPER BSC meeting, during which members would have the opportunity to hear the Director's closing brief on the anthrax exercise. In addition, he noted that for the Board and Ex-Officio members, there would be a FACA orientation session from 8:00 a.m. to 9:00 a.m. prior to convening the second day of the COTPER BSC meeting. He also requested that Board and Ex-Officio members arrive for the COTPER BSC meeting approximately five minutes earlier for a photograph.

Diane Manheim covered logistics pertaining to transportation, meals, and other housekeeping issues.

Dr. Koh thanked everyone for their presentations, insights, and discussions. With no further business posed, he officially adjourned the first day of the COTPER BSC meeting.

Wednesday, August 6, 2008

Call to Order

Dr. Howard Koh, M.D., M.P.H., COTPER BSC Chair
Harvey V. Fineberg Professor of the Practice of Public Health
Associate Dean for Public Health Practice
Director, Division of Public Health Practice
Harvard School of Public Health

Dr. Howard Koh called the second day of the COTPER BSC meeting to order, thanking everyone for an invigorating first day. He indicated that after hearing presentations from two divisions, the group would spend the afternoon making several important decisions with respect to the general operation of the Board in terms of the peer review process for COTPER programs and / or topics of interest. In addition, Dr. Koh noted that Drs. Sosin and Rowitz would be unable to attend and thanked Dr. Barbara Ellis for her hard work on every aspect of this BSC meeting.

Division of Select Agents and Toxins (DSAT)

Robbin S. Weyant, Ph.D. Director
Division of Select Agents and Toxins
Coordinating Office for Terrorism Preparedness and Emergency Response

Dr. Weyant reported that, as reflected in its mission statement, the Division of Select Agents and Toxins (DSAT) is tasked with protecting public health by ensuring safe and secure possession, use, and transfer of select agents and toxins within the United States and regulating the importation of etiologic agents, hosts, and vectors of human disease into the United States. DSAT is one of four operating divisions within COTPER, and works with its partners in the DEO, DSNS, and the Division of State and Local Readiness (DSLRL) to provide COTPER services under the direction of Dr. Besser. Central to the work of DSAT are its four inspection teams: Government Non-Federal Team, Government Federal team, Private and Commercial Team, and Special Functions Team. These teams provide day-to-day, hands-on guidance and inspection services to the regulated community of approximately 400 institutions engaged in select agent work in the United States. A Training Coordinator Position was recently established in recognition of the need for training internally and for the regulated community. The DSAT's Policy and Compliance Group processes compliance actions and works on policy and regulatory documentation of DSAT's work. DSAT also has a Contract Officer in place, given that a significant portion of the DSAT's workforce is comprised of contractors.

DSAT began in 1996 following passage of the Anti-terrorism and Effective Death Penalty Act. At that time, the program was primarily providing oversight of the transport of select agents. The program originated in the Biosafety Branch of the CDC Office of Health and Safety. In May 2000, the CDC Safety Office reorganized and the program was moved within OHS to the External Activities Group, where it remained until 2002. After 2002 it was moved into what was at that time the National Center for Infectious Diseases (NCID). Ultimately, the program was moved to COTPER where it currently resides. While the DSAT program began fairly small in size, following the events of September 11, 2001 and October 1, 2001 (the first identified anthrax case), Congress greatly expanded the authority of this program. This is reflected in the expansion of DSAT's staffing and budget levels.

DSAT works in a highly integrated manner with two federal partners: The United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) and the Department of Justice, Criminal Justice Information Services (DOJ-CJIS). There are three types of select agents (SA). One includes the HHS agents, those of interest to public health, while the two include plant and animal pathogens of interest to agriculture. DSAT works very closely with its colleagues at USDA-APHIS to ensure that the regulations are promulgated and enforced equally. Another important component is the role of DOJ-CJIS, which provides clearance for anyone who applies to work with select agents in the United States.

Other federal partners include the Intragovernmental Select Agents and Toxins Technical Advisory Committee that includes representation from CDC, USDA, National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Homeland Security (DHS), and Department of Defense (DoD). This committee advises DSAT on certain experiments that may or may not be authorized for regulated entities to work on, and to review the select agents list periodically. CDC also has an interagency agreement with NIH to review facilities of foreign grant recipients. With respect to enforcement actions, CDC partners with USDA-APHIS, USDA Investigative and Enforcement Services, Federal Bureau of Investigation (FBI), and the HHS

Office of the Inspector General. CDC also works closely with the Department of Transportation (DOT) to ensure that the select agent regulations are adequately meshed with transportation regulations in terms of shipping these materials.

The Select Agent Program is based on three primary legislative mandates: The Anti-Terrorism and Effective Death Penalty Act of 1996, which tasked HHS with developing a list of agents of concern for public health. It also tasked HHS with developing a system to oversee the transfer of these agents throughout the country, and to require individuals and entities involved in the transfer of these agents to register with HHS. Following the events of September 11 and October 4, 2001, Congress reviewed this program and greatly expanded its authority and responsibilities. Through the USA PATRIOT Act, the DOJ was tasked with developing a system to conduct security risk assessments on individuals who apply to possess select agents. Through the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, USDA was authorized to develop its own set of SA regulations that would cover agents of importance to agriculture. More importantly, it expanded the depths of the regulation to cover not only the transfer of these materials, but also the possession and use of these materials. Interim Final Rules were published jointly by HHS and USDA on February 7, 2003: "Possession, Use, and Transfer of Select Agents and Toxins" (42 CFR 73, 9 CFR 121, and 7 CFR 331). Final Rules were published in March 2005: "Possession, Use, and Transfer of Select Agents and Toxins" (42 CFR 73, 9 CFR 121, and 7 CFR 331). Since that time, there has been one significant change in the Interim Final Rule added in October 2005: "Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments" (42 CFR 73). Currently, there are 72 regulated select agents, of which HHS has sole regulatory responsibility for 21 and the USDA for 31, with 20 overlap agents. These overlap agents are zoonotic, capable of causing disease in both people and animals. The regulation of the overlap agents is an area in which CDC has worked extensively with USDA. DSAT coordinates closely with APHIS with regard to overlap agents so that if an entity has overlap agents, they are required to register with either CDC or APHIS, but not both.

Regarding requirements for entities possessing select agents, an entity must register its facility with either CDC or APHIS for each select agent or toxin it intends to possess, use, or transfer and must designate a responsible official. That individual is responsible for the implementation of SA regulations at their entity, and there are criminal and civil penalties for failure to fulfill these requirements. Entities must implement security and safety measures that will effectively deter theft, loss, or release of select agents. A training program must be in place that adequately trains staff in safety and security. All entities must participate in the theft, loss, and release notification reporting system and are required to report any incident that could potentially result in theft, loss, or release of an SA. Entities must receive approval from either CDC or APHIS prior to engaging in certain functions including: 1) transferring materials from one site to another, making any changes in their registrations, or embarking on new research activities; and 2) Bringing new individuals onto their staff who request to possess, use, or transfer select agents (an FBI security risk assessment is required prior to authorization to work).

In terms of routine activities, there are approximately 400 SA entities currently registered for work in the United States, of which CDC regulates 82% (n=326) and APHIS regulates 18% (n=73). Regarding the profile of the types of entities that CDC regulates, the largest proportion is made up by the government non-federal sector (36%). These are primarily state and local health department laboratories. The majority of members of the Laboratory Response Network (LRN) are registered for possession of select agents. The academic community plays a

significant role in this enterprise as well (30%). Federal laboratories comprise 20% of the laboratories CDC regulated, while the remainder is made up of commercial (9%) and private (5%) institutions. As of June 10, 2008, there are 9,987 individuals with active approvals to access select agents at DSAT-registered entities. With respect to those working in CDC-regulated entities since 2003, 17,111 individuals have been granted access approval after having undergone a security risk assessment. Early on, a lot of catch-up work was done to clear those who were already working in this area at the time of the new regulations. Given that there is currently a five-year renewal cycle for SRAs, an increasing number of risk assessments will expire and must be renewed, which will increase DSAT's workload in this area over the next year or two. Every entity that applies for SA registration must be inspected at least once, and there is a three-year inspection cycle. Since 2003, more than 700 inspections have been conducted. CDC authorizes approximately 500 select agent shipments per year. In addition to routine inspections, special site visits are made if problems are brought to CDC's attention.

The regulations require any laboratory, regardless of whether they are registered, to report the isolation of a select agent (e.g., a clinical laboratory isolating it from a patient, an environmental laboratory isolating it from an environmental source). Once reported to CDC, the agency works with them to ensure the isolate is handled properly and either transferred to a properly registered entity or destroyed appropriately. The resultant dataset has the potential to be a good adjunct surveillance tool, although currently there is a lot of bias in this data because one agent in particular, *Coccidioides immitis*, is endemic in the southwest United States and the vast majority of reports in this dataset are *Coccidioides immitis*. CDC hopes to work with this data as it is an area of potential growth for the future, and has already revised procedures in order to increase the accuracy of the data.

In recent years, some interesting issues have affected the theft, loss, and release reports CDC has received. Between 2003 and 2006, CDC received between 18 to 20 theft, loss, or release reports each year. In late 2006 and early 2007, reporting of these incidents was greatly increased due to CDC publishing a guidance document to the regulated community to help them interpret what should be reported. In addition, there was a high-profile compliance action taken against an SA entity that received a great deal of press, which also greatly influenced reporting. In 2007 there were 60 reports, and CDC expects to receive approximately 100 reports by the end of 2008. DSAT has reconfigured its resources to manage response to this increase in theft, loss, or release reports. The vast majority of the reports pertain to minor incidents which have not posed significant risks to the general public. It is encouraging that this system is helping improve communication between CDC and the regulated community.

The regulations allow for administrative actions, such as the denial of a registration application or revocation or suspension of registration. There are civil money penalties as high as \$250,000 for an individual per violation, and up to \$500,000 for an entity per violation. There is a criminal option of imprisonment up to five years for a violation. Thus far, no one has been jailed for select agent violation. There is also a considerable amount of oversight to DSAT, which CDC welcomes. In recent years, the HHS Office of the Inspector General has reviewed compliance for SA regulations in academic and private entities. They have reviewed CDC's management of the SAP twice. The first survey was conducted around 2002-2003, an extended survey was conducted in 2007, and HHS recently completed a study of CDC's management of SA transfers. CDC considers these reviews as opportunities for improvement.

There have been a number of recent high-profile laboratory incidents, within the United States and internationally, which have been brought to the attention of Congress (e.g., anthrax in Texas, 2002; SARS in Taiwan, 2003; SARS in Singapore, 2003; SARS in China, 2004; anthrax

in California, 2004; and tularemia in Boston, 2005 and Texas A & M, 2007). Last fall, Drs. Besser and Weyant participated in a hearing entitled, "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-laboratories in the United States." At that time, they discussed the improvements that could be made in the oversight of this work with respect to the inspection process (e.g., movement from a trust posture to a trust and verify posture, and provision of more guidance to the regulated community). A Trans-Federal Task Force on Biosafety, which is coordinated by the USDA and HHS, was established shortly after the briefing (November 2007). DSAT has been playing a fairly substantial role in the work of this task force, and has been tasked to examine the select agent realm and the broad research enterprise involving pathogenic biological agents; review current regulations and guidance; and identify any gaps in the regulatory framework. The Task Force is in the process of drafting a White Paper that will be provided to the Secretaries of HHS and USDA.

Recently, Congress has reviewed the DSAT program. In June 2008, Senators Kennedy and Burr introduced the *Select Agent Program and Biosafety Improvement Act* in the Senate. It was also recently read into the House. This act would reauthorize the CDC and APHIS Select Agent Programs through 2013 with enhancements including a National Academy of Sciences review of Select Agent Program impacts; additional criteria for listing select agents; increased information-sharing with the states; guidance on oversight of select agent inventories; and guidance for surge work with select agents. Laboratory safety improvements included minimum biosafety training standards, and the establishment of a broader incident reporting system for incidents in biological laboratories.

With respect to program challenges, DSAT recently completed an internal entity risk assessment of the entities it regulates to identify those which need to be monitored more closely. Given that resources are not infinite, DSAT believes this will be a suitable use of its resources. DSAT is also working on the concept of an Entity Performance Improvement Plan for entities that have compliance issues in an effort to engage entities more proactively in order to assist them with any issues of concern. DSAT also plans to promulgate more guidance documents, to place more emphasis on training activities, and has been working to provide a secure electronic environment for transactions between the program and the regulated community. Program improvements are already underway. DSAT has enhanced inspection procedures, with inspectors now reviewing a greater number of documents before going into the field so that once they arrive at an entity they can interact more closely with the workers in the laboratory. DSAT is also working to improve surveillance processes through follow-up activities for theft, loss, and release reports. The improvement of this system has the potential to be useful in the larger preparedness enterprise. Efforts are also being made to improve DSAT's outreach to the regulated community through guidance documents, training videos (two were developed last year through the select agent website: www.selectagents.gov), and through participation in scientific meetings. DSAT developed a booth that they are taking to major scientific meetings, which are staffed by experts who are available to speak with the scientists attending these meetings about SA issues.

The Etiologic Agent Import Permit Program is conducted in accordance with 42 CFR 71.54- Etiological Agents, Hosts, and Vectors (Effective January 11, 1985), which regulates the importation of etiologic agents, hosts, and vectors of human disease into the United States. As with the SA regulatory program, DSAT also works with partners and stakeholders in the Import and Permit Program: CDC's Division of Global Migration and Quarantine; U.S. Customs and Border Protection, and APHIS. Since 2000, DSAT has issued about 20,000 import permits, at approximately 2,200 per year. With respect to the future, DSAT has faced some challenges and recognized areas for potential improvement pertaining to the import permit program. In 2006, Congress passed the SAFE Port Act, which requires a better integrated IT system that monitors

everything that comes into and goes out of the US, whether this is infectious agents regulated by DSAT or materials regulated by other federal agencies. In order for DSAT to participate in this new system, its IT capacity must be upgraded. This will give DSAT major dividends in terms of efficiency. The Import Permit Regulations were first promulgated in 1985 and have not been reviewed since. Thus, the DSAT is working with their colleagues in CDC's Division of Global Migration and Quarantine to update the current regulations. Oversight and compliance must also be improved, especially for those who want to import highly dangerous materials that are not SAs. While there is already an inspection program for select agent entities in place, there are other entities that might import multiple drug-resistant TB, for example (which is not a select agent). DSAT is faced with the challenge of following up with entities that are importing infectious agents that are not select agents and ensuring that they have the appropriate safety and security measures in place.

Dr. Weyant concluded that the DSAT is comprised of approximately 65 to 70 individuals who each day work to reach the ideal balance of providing enough regulation and oversight so that the critical infrastructure for the United States to respond to emerging infections and SA issues can progress as it needs to. This must be accomplished while ensuring that it is done in a manner that instills confidence about the safety and security of these institutions in those who live around them and in the taxpayers who pay the bill.

Discussion:

Dr. CJ Peters expressed appreciation for the way the SAP has improved over the past six or seven years in that it has become a much smoother operation. Given that none of these agents except smallpox virus are particularly transmissible between humans, it is unlikely that a laboratory would start an epidemic in a community. Dr. Peters' laboratory has emphasized this to their community. However, other areas have experienced significant challenges. With that in mind, he wondered what the counter-balancing achievements were of the SAP.

Dr. Weyant responded that Dr. Peters' institution is a diamond in the crown of the SA enterprise, which is a model program in many ways. They have tremendous outreach with the community, and have not experienced some of the challenges that other locales have when attempting to build new laboratories to conduct SA work. Through interaction with the SAP, there have been significant improvements in safety and security in this work. Realizing the importance of critical research, DSAT is trying to find a balance. They have learned from painful experience that if the local community and the larger community are not confident that the work can be conducted safely and securely, getting the work off the ground becomes problematic.

It seemed to Dr. Mary Gilchrist that in the public health and clinical communities, some of the challenges had been due to strains being deemed more or less potentially pathogenic than they may actually be. She was pleased to hear that DSAT was working on resistant TB and the pandemic strain of influenza, and wondered whether any attention was being paid to strain-specificity in SA work. In addition, she wondered whether the registered select agent organizations and release reports were kept confidential.

Dr. Weyant replied that this is an extremely important issue on which the Technical Advisory Committee spends a considerable amount of time advising DSAT on a strain-by-strain basis with respect to what should and should not be regulated. A portion of the regulation addresses the exemption of certain strains of SAs. For example, if investigators are in the process of developing a vaccine for a strain that is well-documented to be of reduced virulence, they can

obtain an exemption through the work of the Technical Advisory Committee. An up-to-date list of strains that have been exempted from the SA regulations is maintained on www.selectagents.gov. With respect to whether registered select agent organizations were kept confidential, Dr. Weyant indicated that this is a question with which they have wrestled significantly. Through extensive work with the CDC Office of General Counsel, DSAT was recently able to roll out a system by which they can share certain aspects of the DSAT database with state preparedness officials. However, that information is shared in a very highly defined context. State preparedness officials have to demonstrate that they have the appropriate legal mechanisms in place to protect the information. At the federal level, this information is protected from Freedom of Information Act (FOIA) requests, but once it is shared at the state level other mechanisms must be in place. Theft, Loss, and Release Reports are also held confidential.

For the BSC and the public record, Dr. Raskob commended DSAT and acknowledged their difficult balancing act. This is an extremely complicated job, given that should no dire incidents occur, people wonder why this must be done. Yet, when there is a terrible event, people ask why they were not protected. Given this, he stressed the importance of ensuring that COTPER and DSAT had the proper resources to succeed in this mission.

Given the recent publicity about who the alleged perpetrator was from the anthrax attacks in the fall of 2001, Dr. Koh inquired as to what regulations and oversight apply to those experts working with anthrax or other potential terrorism agents.

Dr. Weyant replied that he would have to reserve judgment about this particular situation, given that few details had been released. It certainly pertained to the balancing act with respect to the security risk assessments conducted by DOJ-CJIS, which is given a fairly rigorous list of criteria from the USA PATRIOT Act. Any individual that meets any one of these eight criteria becomes restricted from working with SAs. For example, there is a criterion that relates to a person's mental stability. There must be a well-documented proceeding in order for the FBI to take action and subsequently consult with DSAT regarding whether an individual can maintain access. The FBI has advised DSAT to withdraw access in some cases, so the system has worked in the past.

Dr. Ursano expressed concern with using the term "mental defective," pointing out that at least 20% of the population would qualify as having a psychiatric illness on any given day. He also requested further clarification regarding "transfer" and how an agent is identified and becomes a select agent. He wondered where polonium might fall in terms of when it would be considered a dangerous agent (e.g., if put inside *E. coli*).

Dr. Weyant responded that the definition of "transfer" is a movement of SA materials from point A to point B within the United States. With respect to listed agents, the enabling statute provided them with a few very broad criteria that are used to make determinations of what agents should be listed (e.g., the basic virulence of the organism, how the organism is transmitted, the availability of vaccines and/or other therapeutics that can be used to treat someone who may be infected with one of these, and anything else the HHS Secretary deems important). The process by which something becomes listed runs primarily through the Technical Advisory Committee, and periodically DSAT reviews the list and solicits opinions from the committee regarding whether something should remain or be removed from the list. DSAT is in the process of preparing a couple of Advance Notices of Proposed Rulemaking to be published in the *Federal Register* that will inform the larger community of certain agents not currently listed that are being considered for the list.

Division of State and Local Readiness (DSLRL)

Ms. Donna Knutson, Acting Director

Division of State and Local Readiness (DSLRL)

Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)

Ms. Knutson noted that DSLRL has the same vision as COTPER: People protected—public health prepared, while its mission is to provide support, technical guidance, and fiscal oversight to state, local, tribal, and territorial public health department grantees for the development, monitoring, and evaluation of public health plans, infrastructure, and systems to prepare for and respond to terrorism, outbreaks of disease, natural disasters, and other public health emergencies. DSLRL works closely with the other COTPER divisions, and is organized by an Office of the Director and two branches. The Office of the Director is in the process of being built, with two permanent employees currently in place. DSLRL has close connections with the Strategy and Innovation Office (SIO) and the Enterprise Communication Office (ECO).

DSLRL's grants management function began in the National Center for Infectious Diseases (NCID) in 1999. Grants management responsibility transferred to the Office of Terrorism Preparedness and Response (OTPER), Office of the Director, CDC, in August 2002 when Dr. Gerberding made the decision to move all of the preparedness activities underneath the Office of the Director. A number of staff from NCID wanted to move into this new organization, so they began detailing numerous individuals from across CDC to a program titled the State and Local Preparedness Program (SLPP), which then changed its name to the Division of State and Local Readiness (DSLRL). DSLRL was formally recognized as part of the Coordinating Office for Terrorism Preparedness and Emergency Response through CDC's reorganization process in 2005 and officially became a division at that time. DSLRL does not have the scientific expertise of subject matter experts as is typical throughout CDC. Responsible for coordinating the provision of technical assistance for grantees across CDC, DSLRL has in-house grants management expertise and awards 99.4% of its annual budget through cooperative agreements and contracts, which makes it one of the leanest programs within CDC. The DSLRL's budget for the entire division that remains in-house is less than \$6 million.

The DSLRL budget has increased over time, with the largest amount allocated to the cooperative agreement funds for the Public Health Emergency Preparedness (PHEP) cooperative agreement funding to states. The two types of individuals working on this particular grant in the field are 26 Career Epidemiology Field Officers and 4 Public Health Advisors. DSLRL has a total of 60 FTEs, although the vacancy rate is 35%. This division's budget has been reduced because Congress reduced some of its funding lines, so they cannot afford to hire the number of employees authorized. The DSLRL Office of the Director has four FTEs, the Outcome Monitoring and Evaluation Branch (OMEB) has nine, and the Program Services Branch (PSB), which handles most of the cooperative agreements, has 26 FTEs.

PHEP funding to states through CDC cooperative agreements began in 1999 with a \$40.7 million program, which for CDC standards was fairly large. By 2002, the program was at \$853 million. In 2008, the budget was \$700.4 million in addition to \$100 million specifically for smallpox activities and over \$600 million for pandemic influenza. The President's budget for 2009, which reflects a 9-month rather than 12-month grant period, is \$570.9 million. The House and Senate are negotiating at this point, and it is clear that a nine-month budget period will not persist. Including pandemic influenza dollars, DSLRL's overall 2008 budget was \$953,656,401 of

which the DSLR OD received \$896,941; OMEB received \$7,561,099; and the Program Services Branch (PSB) received \$945,198,361. PSB's budget includes the PHEP cooperative agreement and the Advance Practice Centers cooperative agreement, which goes to National Association of County and City Health Officials (NACCHO). The Centers for Public Health Preparedness grants are moving to COTPER's Science Office and Learning Office for Preparedness Response. The DSLR manages 18 contracts and approximately 100 individual cooperative agreements. Grantees include 62 governmental public health departments, 7 partner organizations (e.g., NAACHO, ASTHO, NALBOH, etc.), and 27 schools of public health.

One of the challenges of this program has been its shifting focus over time, especially given that it is a relatively young program compared to other CDC programs. This program was first authorized in 2000 under the Public Health Threats and Emergencies Act (PL 106-505) or the Frist-Kennedy Bill. This represented an opportunity for public health to rebuild its long neglected infrastructure by training public health personnel, developing an electronic disease detection network, developing a plan for responding to public health emergencies, and enhancing laboratory capacity and facilities. DSLR was reauthorized by the Pandemic and All-Hazards Preparedness Act (PAHPA) of December 2006 (PL 109-417), with much more specific responsibilities for disease situational awareness domestically and abroad, including detection, identification, and investigation; disease containment including capabilities for isolation, quarantine, social distancing, and decontamination; risk communication and public preparedness; and rapid distribution and administration of medical countermeasures. While programmatically the grant began as a competitive grant, the Frist-Kennedy legislation changed that to a formula grant. This means that the DSLR has a certain amount of money allocated by population, so every state knows how much it will receive and competitive awards are no longer required. There are currently 62 grantees rather than a handful of grantees funded through the competitive process.

Under Frist-Kennedy, CDC was the lead agency for developing capacities and capabilities and the program was administered from NCID, with subject matter experts housed there. Under PAHPA/PL 109-417, the formula grants have penalties for non-performance, and CDC is responsible for the operations arm of the grant program, with significant input from HHS and the Department of Homeland Security (DHS). The program is administered by COTPER's DSLR, with subject matter experts housed outside of COTPER. Also under Frist-Kennedy, strategic planning for the stockpile was contained in a whole planning module known as "Focus Area A," and there was no local planning emphasis on countermeasure distribution; some work was begun with state and local experts to develop performance measures; and the focus was generally on bioterrorism. Under PAHPA/PL 109-417, a \$57 million investment has been made in local Strategic National Stockpile (SNS) planning with the Cities Readiness Initiative; countermeasure delivery is a high-level focus for HHS, CDC, DHS, and the Homeland Security Council; and an all-hazards approach has been adopted, with occasional inputs into agent-specific activities (e.g., smallpox, novel flu viruses).

During the lifetime of this grant, an entire new cabinet level was developed (e.g., the Department of Homeland Security). Therefore, it has been challenging to figure out how to work with them in terms of technical capabilities, target capabilities, universal tasks, and understanding what public health's responsibility is in the midst of a public health or other emergency. There is not a great deal of science regarding how to do this right or well, there is substantial emphasis on pandemic influenza, and DSLR is trying to build expertise on exercising and exercise evaluation. DSLR has both strategic and tactical roles. Strategic roles include horizontal leadership across COTPER, CDC; leadership with HHS and other agencies; partnership development and maintenance; and program planning and evaluation. Tactical roles

include the execution of grants and monitoring of program performance. DSLR is aligning with as many of the strategic activities that CDC has in place as possible, including the nine preparedness goals and the public health emergency objectives. DSLR will likely put out a new program announcement in FY 2010 that will align with the public health emergency objectives, and which will be very specialized to some of the current strategies and priorities in Homeland Security Presidential Directive 21, for instance. DSLR also has a responsibility to ensure that they are helping health departments build core public health activities and functions so that they can function in regular events as well as in catastrophic public health emergencies.

DSLR's PSB also has strategic roles, including horizontal leadership across CDC, particularly with subject matter expert interaction; guidance development; and partnership development. PSB's tactical role is to execute the Public Health Emergency Preparedness cooperative agreement. There have been a number of successes: 100% of states have response plans for at least one priority; 100% of states have exercised those plans in the last 12 months; 100% of states have Incident Command Structures in place; and 100% of states can evaluate urgent disease reports 24 hours a day, 7 days a week, 365 days a year.

DSLR's OMEB is approximately two years old. Strategically, OMEB is responsible for the development of measures of capacity, capability, and performance; and development of the vision for data collection and evaluation. Tactically, OMEB plays a major role in training state and local public health professionals regarding data collection and evaluation; interpreting data regarding the performance of grantees; and assuring systematic data collection and warehousing. The Preparedness Emergency Response System For Oversight, Reporting, and Management Services (PERFORMS) houses five years of information from all of the states (e.g., every application, budget change request, mid-year report). DSLR is in the process of determining ways to use these data in a more productive manner to illustrate the gains that have been made. OMEB has developed a program and data reporting framework that includes program management (e.g., fiscal accountability, progress reporting, technical reviews, compliance), capacities in the form of building and maintaining infrastructure (e.g., assessment, planning, training, infrastructure development), capabilities in the form of functional demonstration (e.g., tabletops, drills, exercises, real incidents), and capabilities in the form of performance measurement (e.g., time-based, quality, completeness).

Referring to the "*Public Health Preparedness: Mobilizing State by State Report*" Ms. Knutson stressed DSLR's commitment to present an increasingly clear picture of public health preparedness in the United States. The first report was published in February 2008, with expanded reporting expected in 2010. Data elements include public health workforce; disease monitoring; laboratory testing; and planning, training, and exercising.

With respect to technical assistance to states, a key strategy is to enhance the DSLR's direct technical support for successful preparedness and response capabilities in response to states' and communities' health protection needs within the National Response Framework. CDC will define technical assistance success as rapid identification of priority locations where technical assistance will be most effective; deploying the appropriate level of technical assistance required for those locations within six months of identification; markedly improving preparedness performance based on on-going objective assessments; and clearly defining roles for CDC assets (people, equipment, resources) at sites of emergencies.

Major challenges faced by DSLR include demonstrating performance; maintaining gains already made with decreasing funds; strengthening partnerships with DHS and state emergency management systems; complacency when nothing bad happens; changing focus and short timelines; and exercising and continued quality improvement. More specifically with respect to decreasing funds, of the \$335 million for pandemic influenza activities, \$20 million was allocated to personnel and fringe benefits. Given that this was a one-time emergency supplement, many people crucial to this effort will be lost. While exercising is important, it is costly. Thus, states would like to know what the DSLR would like them to forgo in exchange for exercising, given that they cannot do everything. Thus, the DSLR is continually grappling with several issues in order to maintain balance.

Discussion:

Professor Hoffman requested further information regarding outcome measurement with respect to how DSLR planned to ensure that local entities are utilizing funds optimally.

Ms. Knutson responded that with regard to measuring performance, DSLR has been working closely through the Outcome Monitoring Evaluation Branch with state and local partners through the Association of State and Territorial Health Officials (ASTHO) and National Association of County and City Health Officials (NACCHO) to develop ground-level maps to determine what should be measured with respect to key areas (e.g., biosurveillance, emergency communication, countermeasure delivery, community mitigation). States are provided with a guidance document, which includes 15 pages describing precisely how to measure the six indicies DSLR currently expects states to self-report. While outcome measurement is currently self-reported within very strict guidelines, DSLR hopes eventually to involve program and project officers to determine what is actually occurring in the field. However, the program does not currently have the resources to do so. In terms of fiscal oversight (e.g., ensuring that local entities are utilizing funds optimally), Ms. Knutson stressed that there is substantial oversight of these funds. Since her arrival in COTPER in 2002, she has personally been involved in more than 70 General Accounting Office / Inspector General (GAO / IG) studies, and six IG and six GAO studies are currently underway. The greatest issue they face at present is that some states are paying 100% of an individual's salary under this budget, yet they lend their time and activities to other programs that are also federally funded. There is an effort underway to curtail this.

Dr. Harrauld pointed out that the action plan provided in the Board's materials discussed the development of a risk-based system for improving preparedness capabilities, which inferred that the grant programs would move from a population-based to a risk-based system. He wondered whether this related to what Ms. Knutson said about a formulaic presentation and what the status of this effort was.

Ms. Knutson responded that due to PAHPA legislation, every year the Secretary sets a base amount that every state will receive, which was \$3 million this year. In addition, the risk base upon which DSLR is currently working is basically population-based. Although DSLR attempted to include other factors in order to develop a much more robust risk-based strategy, they were unable to get those approved through the channels. Therefore, while they plan to move in that direction, the best formula for that has yet to be developed.

With respect to technical resources, Mr. Stephens requested additional information regarding what consideration DSLR had given to existing assets and resources already in the field.

Ms. Knutson replied that the Advanced Practice Centers have a lot of information that has not yet been integrated into the DSLR program. They have discovered a great deal of additional information that they would like to ensure is disseminated to the states. In addition, DSLR is considering decentralizing some of its technical assistance, perhaps by placing individuals from headquarters in state and local health departments. They introduced this concept about six months ago. Some states responded positively and welcomed DSLR, while others were more apprehensive about such an arrangement. DSLR is attempting to balance their efforts and to be as creative as possible. If someone needs resources for a short time, DSLR has the ability to place someone on a temporary basis. The CPHP program, public health advisors, and Strategic National Stockpile individuals in the field are part of that effort.

Dr. Besser added that although some people are in the field currently, compared to other large grant programs within CDC, this is one of the largest programs that does not have formal field-based or community-based staff. One reason for having limited staff in the field is that DSLR is one of the few programs that does not take funds off of the top for program support.

Dr. Smith stressed that there is a vast state and local workforce with a great deal of expertise into which DSLR could tap in order to expand their base. While tapping into this workforce would not be traditional with respect to top-down technical assistance, there could be a great deal of value in DSLR finding creative ways to tap into this immense resource.

Ms. Knutson responded that she continually stresses the number of nonfederal resources that could be garnered to expand DSLR's pool; however, they must tap into such resources in ways that are appropriate and that do not strain other state and local level efforts.

Captain Terbush pointed out the tremendous capability of the CPHPs and academic schools of public health throughout the nation. He wondered what the status was of the CPHP program and its future direction.

Ms. Knutson replied that the CPHP Program is in its last year of funding for this particular cooperative agreement, and that 27 schools continue to conduct training and education activities in accordance with the original cooperative agreement. The amount of funds they have to carry out that work is significantly less than last year due to the PAHPA legislation directing DSLR to conduct more research activity with those dollars. Therefore, the extramural research group Dr. Sosin is setting up used some of this allocation to set up research centers.

Dr. Young noted that the new funding opportunity announcement (FOA) due out in spring 2009 will be revised to align more directly with the PAHPA legislation.

Dr. Besser added that organizationally they divided the management of that program into the research component, which is housed in the Science Office, and the training and curriculum development components, which are housed in the Learning Office for Preparedness Response.

Dr. Raskob commended COTPER for requesting that the IOM make recommendations regarding which specific areas of public health systems research should be prioritized. Efforts must now be directed toward advocating for more resources for the public health systems research effort.

Dr. Arnold inquired as to what feedback had been received from states with respect to whether they are able to match funds.

Ms. Knutson responded that PAHPA legislation included a number of new provisions that would begin with federal FY09 funding. One provision is states must contribute 5% of the total award in matching funds. There is also a provision in the legislation regarding maintenance of funding, which basically asks states to declare how much money they are contributing from the general budget side to preparedness in addition to this grant. While the matching component is probably not difficult, it will be burdensome because it must withstand an audit but a great deal of it will be in-kind rather than cash. The cash should be reflected in the maintenance of funding side. States are not pleased about having to calculate this information, so it is more burdensome than not doable. Nevertheless, given that there are provisions for docking funds if states cannot fulfill the matching requirement, it is critically important for states to make these calculations. DSLR does not want to have to withhold funds from their state and local partners.

External Peer Review of COTPER Programs / Procedures & Process Decisions

**Dr. Barbara Ellis, Deputy Associate Director for Science
Science and Public Health Practice Office
Coordinating Office for Terrorism Preparedness and Emergency Response**

Dr. Ellis expressed her deep and personal gratitude to each of the members for their time and assistance in reviewing issues of great importance to COTPER. She explained the purpose of her presentation was to offer an overview of the rationale for conducting an external peer review of intramural COTPER programs, and to lay the groundwork for the decisions the Board must make regarding the primary method used for the reviews; the schedule for reviews and full board meetings; the proposed process for the reviews; and which of the proposed topics would be reviewed in FY09. She reminded everyone that Drs. Gerberding, Besser, and Sosin were committed to increasing the application of science and science-based principles into program practices. CDC has recently updated agency requirements requiring intramural research and non-research programs be externally peer reviewed by BSCs at least once every five years. In addition, the policy specifies that extramural research is to be externally peer reviewed using a model similar to the NIH sequential review process.

While COTPER will determine which programs need to be reviewed and will make recommendations based on programmatic needs, it will be the Board's responsibility to determine the level of engagement they would like to have in the review and oversight process. Programs include intramural research and non-research (e.g., public health practice, core

support services). The scope of reviews will be subject to discussion on a case-by-case basis, and can include single or multiple activities, a portfolio of organizational units or cross-cutting topics, or multiple organizational units across CDC. As Dr. Zaza mentioned, each of the CIOs with preparedness activities have their own BSCs to oversee their peer review processes. However, it is conceivable that for some of the activities in COTPER's portfolio, multiple units may be convened. Depending upon the program or topic, the review may be extremely narrow and focused, or could be quite broad.

Dr. Ellis presented a variety of options for how program reviews could be conducted. The BSCs may elect to utilize either workgroups or subcommittees to assist in the reviews, or may use other external review groups. Regardless of the method used, reports and recommendations should be presented to the full BSC for a consensus opinion. A subcommittee requires one parent BSC member with experts serving as SGEs and is subject to FACA, with all members serving as Special Government Employees and completing financial disclosure forms. The subcommittee method requires a major commitment of time and resources on the part of the subcommittee members. Workgroups convened by the BSC would require that two BSC members serve on the workgroup and provide oversight to the process. Consultants or subject matter experts who serve on ad hoc workgroups would be required to complete conflict of interest forms. External review groups may be appropriately recommended to conduct reviews (e.g., the IOM, National Academies of Science, or other independent bodies) if a topic is extremely broad, very high-level, or over-arching, especially if it pertains to potential change in policy by the US government.

COTPER recommends to the Board that they consider convening BSC ad hoc workgroups as the standardized means of reviewing COTPER programs. The primary reason for this recommendation is that it would require fewer resources than the somewhat cumbersome and time-intensive aspects of forming FACA committees. Given COTPER's diverse group of divisions, it is likely that each ad hoc workgroup might be constituted with different subject matter experts, which would require more flexibility. The ad hoc workgroup method would maintain maximum flexibility in terms of who serves on the ad hoc work group. COTPER also proposed that work group reviews primarily be conducted at CDC's Roybal Campus, with the caveat that there may be some reviews that could be conducted using other formats such as email, teleconference, or other methods. The workgroups would be convened to gather information, conduct research, make observations, draft reports, and analyze relevant issues and facts. Workgroups do not make any decisions or recommendations. They report back to the full Board, which would then make recommendations to Drs. Besser and Gerberding. The final report would be the product of the BSC. In general, work groups only exist for a year or less. If convened by the BSC, then at least two members of the BSC should be on each workgroup. The other members that would constitute the ad hoc workgroups would be nominated by COTPER, with input from the BSC chair and committee co-chairs to ensure that each workgroup is constituted satisfactorily. COTPER proposed a schedule of four ad hoc workgroup meetings (November, December, May, and June) and two full board meetings (April and August) per fiscal year.

The BSC will review and approve how the reviews are conducted as well as their findings. Regardless of the method used in conducting the review, the BSC will be engaged in program reviews and may use different levels of involvement that may include having BSC members actively participate on selected reviews; reviewing the findings of program reviews performed by a subcommittee, workgroup, or other external review group; and providing recommendations and summary determinations on each of the program reviews. Reviews can be conducted by face-to-face meetings, teleconference, email or other means. In terms of minimum review

criteria, the overarching goal of each review is to take into consideration scientific and technical merits of COTPER's programs and to make recommendations regarding how to improve them. This would include review and evaluation of such criteria as significance (e.g., evidence of developing preparedness capabilities), approach (evidence-based methods and strategies), leadership (effective promotion of partnerships in the preparedness community), program staff (adequate expertise), and future direction (evidence of sustaining preparedness capabilities). Additional review criteria fall under the rubric of mission relevance and program impact. Mission relevance pertains to how well the program is matched to the needs of stakeholders and to HHS, CDC, and other public health priorities. A review of program impact is generally retrospective and requires the reviewers to evaluate the degree to which past work has resulted in improvements in public health, and whether the program adequately promoted translation and dissemination of research findings or put new knowledge into action.

With respect to the end result, once the Board makes recommendations regarding observations and the program review, Dr. Ellis stressed that COTPER is highly committed to implementation of the recommendations that are practical to do so, as well as to track progress of the implementation of the recommendations. COTPER will report to the Board regarding the status implementing recommendations one year after the recommendations are issued. In addition, COTPER and Dr. Besser are responsible for reporting the status of external peer reviews. Dr. Besser has delegated that role to the Office of Science and Public Health Practice Associate Director of Science (ADS), who will report to the CDC's Associate Director for Science. Dr. Ellis noted that CDC's Associate Director for Science, Dr. Jimmy Stephens, had joined them during the second day of the BSC meeting.

In conclusion, Dr. Ellis referred members to Tab 7 of their briefing notebook to a draft document titled, "External Peer Review Programs: Procedures, Criteria, & Schedule of Review," which begins to shape policies and procedures for the COTPER external peer review process, procedures, and schedule. She requested that members review the document and provide feedback, indicating that the document would be revised based upon their input and discussions. Dr. Ellis then guided the group through a set of decision points.

Decision Point (1)

Determine the primary method the BSC will use to review COTPER programs and topics:

- The recommendation from COTPER for consideration: That reviews would be conducted primarily by ad hoc workgroups convened by the BSC, with the caveat that there may be some topics or programs that the BSC would recommend other external groups review.

Discussion:

With respect to proposed meetings, Dr. Mazanec wondered why the months specified were chosen, and if it was tied to budget considerations.

Dr. Ellis responded that to some extent the decision was tied to the budget cycle. A full board meeting in September would be problematic, given that CDC is closing out the fiscal year on September 30th. The months proposed for reviews were to allow the workgroups to work through the process and have ample time to prepare their reports that would be vetted back to the program to ensure there were no inaccuracies. Reports would also be shared with Dr. Koh and others before their release to the full Board for review prior to the next BSC meeting. They were attempting to allow for these factors, as well as for the workgroup to reconvene if

necessary to address any additional issues the Board deemed necessary prior to considering a program review to be completed.

Dr. Harrauld inquired as to whether the intent was for the workgroup to meet on-site during one of those months. For example, a workgroup would meet in May or June and report in August.

Dr. Ellis responded that this was correct. Although COTPER was initially proposing that the ad hoc working groups meet on site at CDC, there is flexibility to use email, teleconference, and other means.

Dr. Hamburg wondered whether voting in the affirmative for Decision 1 would preclude deciding later to have the IOM consider a particular question.

Dr. Ellis replied that it would not. After listening to the proposed topics or programs for review, if the Board suggested that a more sustained effort would be required and a subcommittee should be formed, or that it should go to another external body, the Board would have that flexibility.

Mr. Stephens pointed out that other groups that have used BSCs and this process found that there is a great deal of work associated with each review, and that a considerable amount of materials are required at the outset. He thought it was imperative for the Board to be engaged in the most critical issues COTPER believed to be important, and to have mechanisms in place so Board members were not responsible for many reviews beyond the capability of the number of members they have.

Dr. Ellis acknowledged that all of the Board members were extremely busy and that convening at the same time and place and having a quorum would sometimes be challenging. She stressed that the ad hoc workgroup method would allow for increased flexibility and decreased potential burden upon Board members' time. It would also allow Board members with specific expertise and interests to participate in one project review in an intense manner.

Dr. Ursano inquired as to the number of programs and topics COTPER anticipated the Board would review over a five-year span.

Dr. Ellis replied that it was difficult to offer an exact denominator. She referred members to Appendix B in their notebooks to a list of COTPER programs and activities, explaining that a review could be of a single activity or program, encompass multiple programs, or could be cross-cutting across all of COTPER's divisions.

Dr. Besser added that it would be a great contribution to COTPER if the Board could conduct four reviews per year. This BSC is the only group that serves a review function within COTPER, so an initial focus on COTPER's intramural activities was suggested. As time goes on, Dr. Besser thought it would be very exciting to review some of the cross-cutting activities COTPER supports across CDC that may not have been covered by another BSC. Perhaps there could be joint reviews between some BSCs as well.

Mr. Stephens noted that there is a great deal within biosurveillance that is cross-cutting.

Motion and Vote: Decision Point (1)

Professor Hoffman motioned that the primary method the BSC will use to review COTPER programs and topics would be for reviews to be conducted primarily by ad hoc workgroups convened by the BSC (with the caveat that there may be some topics or programs that the BSC would recommend other external groups review). Mr. Stephens seconded the motion. The motion carried unanimously.

Decision Point (2)

Determine rhythm and proposed dates of peer reviews and full BSC meetings. The proposed schedule of review and full BSC meetings was as follows:

| Fiscal Year | Month of BSC Meeting | Month of Review |
|--------------------|-----------------------------|------------------------|
| FY 2008 | August | Not Applicable |
| FY 2009 - 2013 | April, August | Nov, Dec, May, June |

Discussion:

Dr. Koh inquired as to the length of the standard Board meetings.

Dr. Ellis replied that each Board meeting would be approximately two days and each workgroup meeting would be approximately two and a half days.

Dr. Peters indicated that his schedule was such that he would rather arrive the day before a meeting convened and have a full day the next day, as he could not arrive for morning or early afternoon meetings. Others agreed.

Dr. Ursano pointed out that the first topic, "Analyze the end-to-end delivery system for distributing and dispensing medical countermeasures and the underlying concerns regarding these capabilities," was a rather broad task that would require a considerable amount of effort. This task could involve physical visits to a number of sites or interviews with numerous people. It was not clear how this would be done. In addition, he noted that reviewing a delivery system and reviewing a program were very different tasks.

Dr. Koh responded that the workgroup itself would determine the issues and make the decisions about how many meetings would be necessary to cover the scope of a particular topic or program.

Dr. Ellis agreed that it would be incumbent upon the COTPER Program as well as the BSC chairs to determine the scope of the topic for review, the number of meetings, and whether an additional committee might be required. Budget would also have to be taken into consideration.

Dr. Harrauld asked where their actual "marching orders" would originate.

Dr. Ellis replied that for the initial topics, COTPER and the programs made a self-assessment, worked with leadership and the Science Office to ensure that the scope was clearly defined, and this was reflected in the proposed topics for the FY 09 review.

Dr. Besser added that the proposed topics were a starting point. With regard to countermeasure distribution, COTPER raised what they believed were the critical questions to ask. The

workgroup may determine that either issues were missing or the scope needed to be pared down. They could engage in discussions with COTPER to determine whether there were certain components of the review that a working group felt comfortable undertaking and other components they may prefer to defer to another external group. He thought it was within the purview of BSC to help COTPER craft the scope of the reviews.

Motion and Vote: Decision Point (2)

Professor Hoffman motioned that the schedule tentatively be April and August for full Board meetings with possible meetings in November, December, May, and June for ad hoc working groups. Dr. Peters seconded the motion. The motion carried unanimously.

Decision Point (3)

Review proposed process, specifically recommendations that:

- Primarily the reviews will be conducted by BSC ad hoc workgroups at the CDC (Roybal Campus) location as opposed to email or teleconference, although these other means to conduct a review may be considered when appropriate;
- How ad hoc workgroups will be constituted (e.g., COTPER ADS assigns DFO for each workgroup; the BSC will assign the ad hoc workgroup chairs; COTPER will provide the BSC chair and work group co-chairs with proposed nominees for the ad hoc workgroups);
- How observations from ad hoc workgroups will be reported (proposed by written report), process whereby the BSC will provide recommendations, and means of implementation and tracking of recommendations (COTPER will report annually to the Board on their success in implementing the recommendations made).

Discussion:

Dr. Koh noted that the accountability theme running through the last part of Decision Point 3 was very exciting for the Board, given that they would have the opportunity to make some thoughtful recommendations and see them implemented and tracked over time.

Mr. Stephens and Dr. McKenzie pointed out the importance of recommendations being actionable versus the standard recommendation that more funding is needed. That is, the program must be able to act upon the Board's recommendations in a productive fashion.

Regarding selecting members for the ad hoc working groups, Dr. Harrald suggested that they use the Board as a whole for suggestions for nominees, not just those who volunteer for a particular workgroup. While Board members may not have expertise in all of the areas, they know others who do.

Dr. Ursano suggested the following language for COTPER's protection, "COTPER, with the advice of the BSC and external advisors, will provide the BSC with . . ."

Dr. Adirim inquired as to how many people would be on each workgroup.

Dr. Ellis responded that COTPER had resourced a total of nine, although it could be more or less. It may prove challenging to convene more than nine people at the same time.

Dr. Besser stressed that COTPER anticipated that this would be a highly interactive process. For example, between the time that a working group meets and the finalization of their report, there would likely be back-and-forth discussions with the program. There is a major commitment on the part of the programs to be reviewed to provide the information working groups need. This information would allow the recommendations will be fleshed out enough that they can be implemented if the full Board concurs with the findings when the full Board convenes in April 2009.

Dr. Quinlisk wondered if there would be any kind of input from external partners as part of the review process.

Dr. Ellis responded that there could be depending upon the topic and whether seeking such input was appropriate. She anticipated that the workgroups would be interviewing partners, or obtaining feedback from partners and stakeholders. One of the reasons to have two BSC members present on each ad hoc working group is to ensure that there is a sense of tracking individual recommendations that may be made from the ad hoc workgroup members.

Dr. Besser added that one reason for the presence of liaisons was to tap into the groups the liaisons represent to participate in the workgroups. A working group review of one of COTPER's programs that did not include those who were interacting with the program or using the outcome of that program would not be very useful.

Dr. Peters inquired as to whether there would be a budget to bring particular stakeholders to a particular place for working group members to speak with them. For example, he wondered whether a group with an arrangement with CDC may have a budget for such a meeting.

Dr. Ellis responded that if an ad hoc working group determined that it would be important to interview stakeholders or partners, COTPER would bring those partners in subject to the availability of funds.

It seemed to Dr. Raskob that as part of the process, COTPER and the assigned chair and co-chair for a particular workgroup should feel free to call on any of the liaisons or other groups to tap into the organizations to pull in expertise relevant to the topic.

With regard to discussions about the possibility of potential meetings elsewhere, Dr. Hoffman pointed out that it was likely that the selection of the Roybal Campus was to reduce the burden with respect to meeting organization.

Dr. Ellis replied that all of COTPER's programs are on the Roybal Campus, which was the primary reason for selecting it as the location for face-to-face meetings.

Dr. Besser added that while there should be flexibility in the decision in order to avoid having to re-vote at a later time, it would be difficult as a rule from a logistical perspective to support meetings elsewhere. Nevertheless, a situation may arise in which a workgroup may need to meet at a stockpile site, at a location in conjunction with another meeting taking place, or in D.C. if the hub of activity was there.

Motion and Vote: Decision Point (3), Part A

Professor Hoffman motioned that the physical meetings of the ad hoc workgroups would be conducted primarily at CDC's Roybal Campus. Dr. Muckstadt seconded the motion. The motion carried unanimously.

Motion and Vote: Decision Point (3), Part B

Professor Hoffman motioned that the BSC ad hoc workgroups will be constituted with the following roles and responsibilities: COTPER Associate Director for Science (ADS) will assign the Designated Federal Official (DFO) for each workgroup; the BSC will assign the ad hoc workgroup chairs; COTPER, with the advice of the BSC and BSC liaisons, will provide the BSC chair and co-chair with proposed nominees for the ad hoc workgroups. Mr. Stephens seconded the motion. The motion carried unanimously.

Motion and Vote: Decision Point (3), Part C1

Professor Hoffman motioned that the ad hoc workgroups will report their findings to the BSC through written reports. Dr. Muckstadt seconded the motion. The motion carried unanimously.

Motion and Vote: Decision Point (3), Part C2

Professor Hoffman motioned that COTPER's ADS is responsible for tracking the implementations of the recommendations and that the progress of the implementations will be reported to the full board annually. Dr. Muckstadt seconded the motion. The motion carried unanimously.

Decision Point (4)

Review initial proposed criteria for those programs that the BSC will peer review (Appendix A): It was recommended that the BSC agree that each ad hoc workgroup use Appendix A provided in the notebook as guidance, but clearly delineate and be able to articulate what criteria they used in the review. This was proposed in order to allow versatility in the reviews, because depending upon the program, there could be some criteria that may be more specific for particular program areas. The criteria are primarily based on the CDC guidance that Dr. Jimmie Stephens and the Office of the Chief Science Officer articulated in a draft that had not been finalized at the time of this meeting. The primary initiative and framework for conducting the reviews is to consider the scientific and technical merits of the program and / or cross-cutting areas and mission relevance and program impact retrospectively. While the materials provided to panelists in Appendix A differed slightly (significance, approach, mission relevance and program impact as appropriate, program staff, and future direction), it was noted that they could all be shaped under these three rubrics (e.g., scientific and technical merits of the program, mission relevance, program impact).

Discussion:

Dr. Koh asked whether the proposed criteria had been used by previous boards with some level of success.

Dr. Stephens replied that they had. However, he thought the issues before the COTPER BSC were going to be somewhat different because the nature of the COTPER programs differed from others. Other BSCs are reviewing topics that are a mixture of a heavy dose of internal research plus programs. With that in mind, he suggested maintaining flexibility in terms of what set of criteria made the most sense.

Dr. Hamburg found the criteria suggested to be comprehensive, but suggested a more concrete focus on whether a program most effectively utilizes available resources and partners, and enables broader connectedness and / or coordination.

For Dr. Ursano, this raised the question of how an area for review would come to the Board initially. This was reminiscent to him in many ways of an IOM approach, which usually came with a description of the problem and the questions being asked. That allowed for what might be the standard tasks for 90% of what came before them, but there might be unique issues as well. He wondered whether they were approving the criteria forevermore or if these were relevant criteria to be considered as a starting point when areas were identified for review. For example, they might be asked to review the interface among three programs all relevant to accomplishing a common goal, in which case the criteria might be quite different.

Dr. Ellis replied that these represented the minimum criteria, looking substantively to the scientific and technical merits of the program, mission relevance, and program impact.

Dr. Hamburg found the proposed criteria to offer a useful framework for thinking about key aspects of topics and programs. Obviously, not all of these would apply to all reviews undertaken. She cautioned that they not lock themselves into some type of metric that ultimately would make their efforts not useful.

It appeared to Dr. Ursano the commitment to each of the workgroups from internal staffing would be substantial, so he wondered whether there was a plan to dedicate an office or several staff members fulltime this effort.

Dr. Ellis responded that there were such plans in place. It is a substantial commitment on the part of the programs to participate in these reviews as well.

Dr. Mazanec emphasized that the proposed criteria should serve as a guide, particularly given that some of the wording in the questions posed need further clarification and definitions.

Dr. Besser stressed that a workgroup could not likely use the proposed criteria as a checklist, given that the five program areas COTPER was asking the Board to consider were very different qualitatively. How these questions would apply and which would apply would vary.

Mr. Stephens wondered in which of these areas anticipated or projected budgets or financials were covered in terms of the overall impact. This also relates to adequacy, sustainability, and feasibility. There is an interlinking between the performance goals and the reality of the financial piece. For example, a working group might recommend either a re-allocation of funds or changing the scope of the program to make sure that they have achieved the criteria included.

Dr. Ellis replied that some of these issues covered some issues in program impact, although it does not speak specifically to the budget issue. She agreed that this is not intended to be a checklist, and indicated that it could be revised to clearly reflect budget issues.

Dr. Besser added that he would find it useful if workgroups took into consideration whether resources are appropriate for the mission a program has, and if not, what advice the workgroup would offer with respect to prioritization of activities.

Motion and Vote: Decision Point (4)

Professor Hoffman motioned that that the working groups use as a starting point the criteria delineated in Appendix A under Tab 7, though they will have to refine the criteria as appropriate. Mr. Stephens seconded the motion. The motion carried unanimously.

Decision Point (5)

Review proposed topics for peer review in FY09 and determine which COTPER programs will be peer reviewed by the BSC and in which order. Potential topics:

1. Medical Countermeasure Delivery (Distribution and Dispensing) Capability (DSNS)
2. Director's Emergency Operations Center (DEOC) (DEO)
3. CDC Emergency Response Plan Exercise Program (DEO)
4. Allocation Process for CDC's "Public Health Emergency Preparedness and Response" Budget (OD/SIO)
5. Technical Assistance for Preparedness and Response (DSLRL lead)

To set the stage for the discussion and vote for Decision Point 5, Dr. Koh invited the division leaders to share additional insights into what some of the issues / tasks of the workgroups might entail. He explained that the charge to the board was to deliberate which of the potential topic areas they would select as the first two to four that would be most appropriate for the ad hoc workgroups to review during FY09.

Dr. Mark Wooster (Filling in for Mr. Phillip Navin) Director's Emergency Operations Center (DEOC)

Dr. Wooster thought it fortunate that the BSC meeting was convened during both a real response (e.g., Hurricane Eduard) and the choreographed chaos of a full-scale anthrax exercise. Looking at the Director's Emergency Operations Center (DEOC) as a system without these activities going on would be difficult to imagine. DEO would like the BSC to assess the DEOC from a systems perspective, either as a whole system or as a subset of that system, such as the Operations Department within the entire IMS structure. Another way to assess the DEOC would be by considering whether the IMS structure as a standardized format across all emergency response was the right structure for a public health emergency response center. A third possibility would be to assess the DEOC with respect to the interface between CDC's traditional mission of public health response (e.g., having to make decisions and act based upon a high level of uncertainty) and the more academic response of having to have all the information before making the decision. DEO proposed very specific areas in which they believed the Board could truly engage to help the Division determine how they could do their job of response more effectively, how they could become more effective at integration of the public health mission and the response mission at CDC, and how they could merge the gap between response and academic public health. DEOC would like input regarding how they could best use the exercise process to bring CDC together to focus on CDC's public health response

mission, and whether they are conducting themselves in accordance with DHS and HHS policies and procedures.

Ms. Donna Knutson
Division of State and Local Readiness (DSLRL)

Ms. Knutson indicated that the DSLRL proposed that the Board help them with technical assistance advice in terms of whether there is a better model for technical assistance than the one currently being used (e.g., gathering individuals from throughout the agency to go to states to identify technical assistance needs), and a better way to increase the pool of available resources to provide technical assistance. What are the advantages and / or disadvantage to having CDC staff go to places versus having individuals assigned to the states full time? DSLRL would like to better understand how to evaluate whether the way they allocate their resources is actually improving preparedness for each of the state and local health departments.

Dr. Stephanie Zaza
Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)

Regarding the topic of the fiscal allocations process for CDC's "Public Health Emergency Preparedness and Response" Budget (OD / SIO), Dr. Zaza pointed out that the purpose of an annual peer review of this process would help COTPER think through the validity, reliability, and transparency of this process and to make improvements or major overhauls in either direction. Their initial questions are focused on the process itself, and whether the results of that process are as strategic as they could be, given the various constraints she reported during her presentation the previous day.

Mr. Greg Burel
Division of Strategic National Stockpile (DSNS)

With respect to medical countermeasure delivery (distribution and dispensing) capability, Mr. Burel pointed out that a major issue is the perception, real or not, that the entire delivery framework from the time materiel leaves CDC, until the time it is actually distributed to the person in need, may be too long or may not be able to accomplish certain objectives. There are distinct phases of this process, and most of the suggestions have essentially been the result of brainstorming sessions. However, none of these efforts has considered the entire process. It does not help to shorten the first phase if that does not ultimately get anything to anybody any quicker. DSNS would like for the Board to assess what the program is currently doing, help them determine how to better communicate their capabilities, and make that information very concrete in order to help everyone understand what can or cannot happen in reality. It is important to identify the gaps in their capabilities and to better understand how to target the many good suggestions they have been given and determine other means by which to fill those gaps.

Discussion:

Professor Hoffman pointed out that some of the areas were very CDC-specific, such as budgets, while other issues seemed far more general and ambitious. In addition, other work is being done in some areas such as countermeasures (e.g., an IOM study). She inquired as to how they would ensure that the BSC was not duplicating efforts.

Dr. Adirim inquired as to whether they were to review the programs or the processes the programs run.

Dr. Ellis responded that it could be programs or processes depending upon what the program's needs are. What they had just heard from the division directors regarded issues that continue to arise, and need thoughtful response.

Dr. Besser added that each of the proposed topics could be cast very widely. Most of these topics, with the exception of CDC's "Public Health Emergency Preparedness and Response" Budget, are being dealt with in some way by other groups. However, as a workgroup is being formed and is learning about the terrain, the perspective that these other reviews are taking is different. There are questions that remain for CDC from a programmatic perspective that would not be duplicative of other efforts. Many groups are examining countermeasure distribution, but there are specific questions related to the COTPER programs that would benefit from a review by the COTPER BSC. All of the proposed topics are areas which would benefit greatly from BSC input. Given that they cannot review everything at once, achieving some real success with the first couple topics would be valuable. Dr. Besser stressed that the information provided about the proposed topics in the members' packets was essentially a teaser to initiate conversation around a more focused approach.

Given the range and scope of the topics and the potential limitations of the Board's capabilities and capacity, Dr. Ursano suggested that each program undergo a self-study with outside consultants who are funded. He was thinking particularly of the DEOC, given that no one on the Board runs an operational center. If DoD, HHS, and DHS have assessed the DEOC program, for example, the Board could begin by reviewing those assessments. The Board would then review the self-study and perhaps submit it to four other DEOC's for their input.

Dr. Peters pointed out that given the importance of the proposed topics, one of the most important roles the Board could play would be to help garner better resources by highlighting areas in which the resources are insufficient. He supported the area of countermeasures, given that pills matter very little unless they are distributed to the people who need them. While a number of ideas have been suggested, the proposal that made the most sense to him was to have the postal workers serve as distributors. However, it is not clear whether postal workers will want to do so or how they will be guarded.

Dr. Raskob suggested that the Board seek input from the liaison members. From his perspective as someone working out in the field, his suggested priorities were 1, 3, and 5. If he had to narrow it to two, he would suggest 1 and 5.

Dr. Hamburg agreed that the Board could make a significant contribution to 1 and 5. She also raised the nuclear / radiological issue, expressing her discomfort with the Board not addressing it, given that there would likely be an expectation that there would be expertise in that area.

Dr. Besser responded that the nuclear / radiological area was a cross-cutting issue, which would be interesting to address across BSCs. The primary focus for those programs at CDC is in the National Center for Environmental Health (NCEH). This is a cross-cutting issue because it falls within preparedness work overall in terms of goal action planning and identifying gaps, and in terms of resource allocation to various scenarios. While he did not know whether NCEH's BSC had reviewed that program or what stage they were with preparedness, they identified primary gaps and put forward a proposed budget for those activities.

Mr. Stephens inquired as to how NCEH was tying that back into state and local preparedness, overseen key COTPER programs.

Dr. Besser replied that at this point, it was primarily through All-Hazards and examining the functional areas that cut across. On the laboratory side, NCEH is developing assays that would hopefully become part of a laboratory response network for nuclear / radiological issues. However, this effort remains in the developmental stage because the assays are not ready to take to scale.

Mr. Stephens pointed out that biosurveillance was another cross-cutting area in which they might interact with other BSCs, given that some of the areas are closely and critically tied into some of the activities that the COTPER programs oversee and administer.

Dr. Ellis responded that a subcommittee was being formed through the Advisory Committee to the Director of CDC specifically regarding biosurveillance activities, which planned to meet the following week. The committee members will divide into eight task forces to deal with different aspects of biosurveillance and implementation of the biosurveillance strategy that Dr. Sosin and his group have been working on. In response to Dr. Stephens' inquiry regarding whether this group would report to the COTPER BSC, Dr. Ellis said she expected that they would make recommendations and develop reports.

Dr. Koh added that his understanding was that it was within the purview of the COTPER BSC to request presentations on topics such as that.

Dr. Harrauld pointed out that the way the second priority was written steered him in the wrong direction. The DEOC is a physical place on which a lot of money has been spent; therefore, it is obviously not very interesting to comment on how well or not it has done. The broader question for the Board to address would regard the decision and the information management processes.

Dr. Koh suggested rephrasing Topic 2.

While from a public health director's stand point Dr. Arnold acknowledged that 1 and 5 were important, he thought 3 (CDC Emergency Response Plan Exercise Program) was extremely important due to increasing community-engagement in the preparedness effort, particularly through exercises. He pointed out that there were issues of disparity with regard to the composition of the Board and assessment of community factors (e.g., there are no neonates, people with disabilities, or those from different ethnic groups). By prioritizing 3, he saw the possibility of developing potential partnerships with the private sector, community-based organizations, people in faith-based communities, etc. He stressed that one of the positive points in terms of community engagement was their ability to affect the legislative process as a voting pool and to force legislators to address the issues brought forward on the public health agenda. This in turn can have a positive impact on budgetary strength. For example, due to

people speaking on their behalf, his agency was the only one which did not experience budget cuts this year, although every other agency had a 4% to 5% budget cut.

Dr. Wooster agreed that determining better ways of exercising and the ability to respond to local populations would be a beneficial contribution from the BSC.

Dr. Adirim agreed with Dr. Harrauld that examining the decision making process was doable, while 1 and 5 were major, broad topics that would be much more difficult. Perhaps starting with those things that were do-able and that were priorities of the agency would be the best course.

Dr. Smith pointed out that without a strategic approach to how budgeting is done, COTPER would never be resistant to chasing the disease of the week or be able to stand up to a strategic plan which they had very carefully thought out. It would be a shame for all of the programmatic efforts to fall prey to the whims of budgets.

Dr. Hamburg agreed that budget was extremely important in driving priorities and engaging a set of critical players. She thought it was imperative to raise the budget process to a higher level within CDC to ensure integration and coordination.

Dr. Zaza responded that over the last few years the question had arisen about how to take this to scale within the agency. There have been so many changes that have not been yet well-integrated and they have been moving slowly with that. However, recommendations from the Board about what pieces are working well and are not only sustainable for COTPER, but also are scalable for the rest of the agency would be tremendously useful beyond COTPER.

Dr. Koh recapped that there seemed to be a lot of support for priority topic 1, although there remained concerns about the scope and how the Board would tackle that issue. Dr. Ursano raised the possibility of self-study. Regarding priority topic 2, it seemed that most people did not feel they were DEOC experts and if they assessed this topic, it would be from the perspective of the decision-making process rather than the DEOC itself. There seemed to be a fair amount of interest in priority topic 3, especially because it would bring in partners from outside CDC and COTPER. Priority topic 4 received some attention, and there was some interest in priority topic 5. It seemed that if they had to choose four areas to start, these would be 1, 3, 4, and 5.

Dr. Harrauld urged the inclusion of priority topic 2, given that if the decision process does not work, an abundance of resources will make no difference as observed with Hurricane Katrina.

Captain Terbush thought priority topic 2 was do-able, pointing out that there is a lot of precedence for linking operation centers and the rapid decision making process. There is some additional data and examples that could be brought to bear, particularly with the idea of further linking, sharing, and critical information requirements.

Dr. Besser indicated that from a COTPER perspective, issues 1 and 5 were critically important to him and the agency and the budget is primarily allocated to these. The stockpile and the state program together represent approximately \$1.4 billion. Given that this is the largest investment they make, any suggestions on improvements in those two areas would have major resource and programmatic implications. He stressed that all of the topics were included because they were important to COTPER, so choosing two was like picking favorite children.

Dr. Adirim wondered if perhaps 1 and 5 could be reworded and scoped down somewhat. Dr. Koh responded that doing so would be up to the chair and co-chair of the workgroup.

Motion and Vote: Decision Point (5), Part A

Professor Hoffman motioned that the first two topics for peer review would be: Topic 1 (Medical Countermeasure Delivery) and Topic 5 (Technical Assistance for Preparedness and Response). Dr. Muckstadt seconded the motion. The motion carried unanimously.

Dr. Hoffman asked whether they were committed to having four topics to be completed within a year, or if perhaps they could begin more slowly.

Dr. Ellis responded that COTPER hoped the Board could decide on four topics to be completed during FY 09 so they could begin planning and working with programs. She liked the idea of trying to mix a heavy topic with others that were more focused, given the short timeline for programs to prepare for November to December reviews, and the very busy BSC chair and co-chairs.

Dr. Koh noted that priority topics 2, 3, and 4 remained from which to select the remaining two priorities.

Dr. Harrald suggested that priority topic 2 be the third priority, and he agreed to serve as Chair. He suggested rewording it to, "Review the incident management and decision process as managed in the DEOC."

Captain Terbush volunteered to co-chair priority topic 2.

Dr. Zaza pointed out that it would be an almost impossible task to ask the same people in the DEO to engage in two reviews back-to-back in November and December. She suggested splitting up 1 and 5, conducting priority topic 1 early followed by one of the DEOC priorities, and 5 later with the other DEOC one. That is, if they preferred to assess the DEOC and the exercise program, they should split those up across time.

Dr. Ursano suggested moving Dr. Hamburg to 4, and he agreed to move to 5.

[Note: No actual motion was made or vote was taken with respect to the third and fourth priorities].

Decision Point 6: Determine BSC Ad Hoc Workgroup Chairs and Co-Chairs

The following decisions were made with respect to members of the Ad Hoc Workgroups, in order of priority:

| Priority Topic Area | Ad Hoc Workgroup |
|---|--|
| 1. Medical Countermeasure Delivery (Distribution and Dispensing) Capability (DSNS) | Dr. Muckstadt, Co-Chair Dr. Peters, Co-Chair |
| 5. Technical Assistance for Preparedness and Response (DSLIR lead) | Mr. Stephens, Co-Chair Dr. Ursano Dr. Rowitz, Tentatively Nominated |

| Priority Topic Area | Ad Hoc Workgroup |
|--|---|
| 2. Director's Emergency Operations Center (DEOC) (DEO) [REWORDED: Review the incident management and decision processes as managed in the DEOC] | Dr. Harrald, Chair Captain Terbush, Co-Chair |
| 4. Allocation Process for CDC's "Public Health Emergency Preparedness and Response" Budget (OD / SIO) | Dr. Hamburg, Tentatively Nominated Dr. Hoffman, Co-Chair |

Closing Discussion / Future Agenda Determinations

Following the determination of the top four priority areas, establishment of their respective ad hoc working groups, and placement of some working group members, general discussion continued.

Discussion:

Dr. Koh inquired as to whether Dr. Ursano's idea of self-study was a feasible option.

Dr. Ellis responded she thought it would be; however, she wanted to carefully work through that and come back to the Board after having an opportunity to discuss the option further with Drs. Besser, Sosin, and the program about the best way forward on that.

Dr. Besser added that he learned from Dr. Stephens that the self-study method is used by other BSCs and offices. COTPER could reach out and learn from other groups who have used it, taking some of the burden off the workgroups and placing it back on COTPER.

Dr. Stephens suggested seeking information from the following groups which have used the self-study model: 1) NCEH used a self-review followed by verify and clarify with the Board, and ultimately a review by the Board; and 2) NIOSH went through a process with the National Academies, in essence developing a self-review.

Dr. Ellis reminded everyone that COTPER would like to hear the members' comments on the draft document located in Tab 7 that outlines the proposed process and criterion review.

Dr. Harrald suggested that the chairs and co-chairs report back to the full Board in a short timeframe with a revised problem statement for each of the priority topic areas.

Future agenda items suggested during this discussion included the following:

- Nuclear / radiological issues
- Isolation and quarantine strategies which perhaps should be an on-going agenda item (Dr. Quinlisk will seek information pertaining to a group currently examining isolation and quarantine, from whom a report is due out in June 2009)
- Sheltering in place (one way to deal with the nuclear issue is to include it with quarantine and sheltering in place)

- Interdisciplinary approach to preparedness and exercising—across the realm of the science

Public Comment Period

No public comments were offered during this meeting of the COTPER BSC.

Adjourn / Certification

With no further business raised or discussion posed, Dr. Koh officially adjourned the first COTPER BSC meeting.

I hereby certify that to the best of my knowledge, the foregoing minutes of the August 5-6, 2008 COTPER BSC meeting are accurate and complete:

10/27/08

Date

/S/

Dr. Howard Koh, M.D., M.P.H.
COTPER BSC Chair

ATTACHMENT 1
COTPER BSC Participant List
August 5-6, 2008

Chair

Howard Koh, M.D., M.P.H.

Harvey V. Fineberg Professor of the Practice of Public Health

Associate Dean for Public Health Practice

Director, Division of Public Health Practice

Harvard School of Public Health

Designated Federal Official

Dan Sosin, M.D., M.P.H. Associate Director for Science COTPER - CDC

Participating Board Members

Margaret Hamburg, M.D.

Senior Scientist Global Health and Security

Initiative Nuclear Threat Initiative

John Harrauld, Ph.D.

Director, George Washington Institute for Crisis, Disaster, and Risk Management

Department of Engineering Management and Systems Engineering The George Washington University

Sharona Hoffman, J.D.

Profession of Law and Bioethics, Case Western Reserve University School of Law

Ellen Mackenzie, Ph.D.

Professor and Chair, Department of Health Policy and Management, The Johns Hopkins University Bloomberg School of Public Health

John Muckstadt, Ph.D.

Professor, School of Operations Research and Industrial Engineering - Cornell University

Clarence Peters, M.D. (by teleconference on August 6, 2008 only)

Professor, Department of Microbiology, Immunology, and Pathology -University of Texas

William Stephens, M.S.

Advanced Practice Center Manager, Tarrant County Public Health

Robert Ursano, M.D.

Chairman, Department of Psychiatry, Uniformed Services University of Health Sciences

Ex-Officio Members

U.S. Department of Health and Human Services (DHHS)

Mary Mazanec, M.D., J.D.

Director, Division of Public Health Systems, DHHS, Office of the Secretary Office of the Assistant Secretary for Planning and Evaluation, Office of Health Policy

U.S. Department of Homeland Security (DHS)

Terry A. Adirim, M.D., M.P.H.

U.S. Department of Homeland Security, Medical Advisor - Office of Health Affairs, DHS

James Terbush, M.D., M.P.H.

U.S. Department of Defense

CAPT, USN, MC, FS, N-NC Command Surgeon

Liaison Members

Association of Public Health Laboratories (APHL)

Mary Gilchrist, Ph.D.

Director, Bureau of Laboratory Sciences, Commonwealth of Massachusetts Department of Public Health

Association of Schools of Public Health (ASPH)

Gary Raskob, Ph.D.

Dean, College of Public Health, University of Oklahoma Health Sciences Center College of Public Health

Association of State and Territorial Health Officials (ASTHO)

Damon Arnold, M.D., M.P.H.

Director, Illinois Department of Public Health

Council of State and Territorial Epidemiologists (CSTE)

Patricia Quinlisk, M.D., M.P.H.

Medical Director and State Epidemiologist Iowa Department of Public Health

National Association of County and City Health Officials (NACCHO)

Karen Smith, M.D., M.P.H.

Director of Public Health Napa County Health and Human Services Agency Public Health Division

CDC Participants

- Julie Gerberding, MD, Director CDC
- Richard Besser, MD, Director COTPER
- Barbara Ellis, PhD, Acting Senior Science Advisor, OSPHP COTPER
- Greg Burel, Director Division of Strategic National Stockpile, COTPER
- COL Ted Cieslak, M.D., Department of Defense Liaison, COTPER
- Deborah Gould, PhD, Workforce and Career Development Officer, COTPER
- Donna Knutson, M.S.Ed, Acting Director Division of State and Local Readiness, COTPER
- CAPT Mary Lambert, MN, RN, Chief Management Officer, COTPER
- Phil Navin, MHA, Director, Division of Emergency Operations, COTPER
- Ann O'Connor, MPA, Enterprise Communications Officer, COTPER
- Rob Weyant, PhD, Director, Division of Select Agents, COTPER
- Kem Williams, MBA, Director, Division of Business Operations, COTPER
- Andrea Young, PhD, Preparedness and Response Learning Officer, COTPER
- Stephanie ZaZa, MD, MPH Strategy and Innovation Officer, COTPER
- Diane Manheim, , COTPER
- Marinda Logan, COTPER
- Kim Gadsden-Knowles COTPER
- Naomi Williams, COTPER
- Dionne Mason, NCHM CDC
- Denise Casey, COTPER
- Lisa Lee, OCSO, CDC
- Terrance Jones, COTPER
- Joseph Igietseme, NCPDCID, CDC
- Mark Biagioni, COTPER
- Bob Phillips, COTPER
- Linda Tierney, COTPER
- Stacy Brawner, COTPER
- Mike Latham, COTPER
- Diane Caves, COTPER
- Wanda King, COTPER
- Jerilyn Gilbert, COTPER
- Alyson Richmond, COTPER
- Valerie Kokor, COTPER
- Nan Keenan, COTPER
- Stephanie Weir, COTPER
- Charles Rafferty, COTPER
- Kim Lindsey, COTPER
- Christa Singleton, COTPER
- Keesler King, COTPER

- Craig Thomas, COTPER
- John Decker, NIOSH, CDC
- Pam Lutz, COTPER
- Monique Salter, COTPER
- Mildred Williams- Johnson, COTPER
- Steve Adams, COTPER
- Karen Galloway, CDC
- Nataja LaRocque, NCPHI, COTPER
- Sue Gorman, COTPER
- Ikeysha Tucker, COTPER
- Sabrina Debose, COTPER
- Richard Henkel, COTPER
- Lazenias Harris, NCPHI, CDC
- Lori Bane, COTPER
- Medhat Henein-Azer, COTPER
- Robert Marrero, COTPER
- James Love, COTPER
- James Blaine, COTPER
- Gwendolyn Cattedge, COTPER
- Andrea Anason, COTPER
- Mary Lercher, CDC
- Tony Moulton, OSI, CDC
- Craig Thomas, CDC
- Andrew Hopkins, COTPER
- Mike Latham, COTPER
- Capt. Kathleen McDuffie, NCHM, CDC
- Gregory Smith, COTPER
- Sheila Stevens, COTPER
- Prachi Mehta, COTPER
- Janice McMichael, COTPER
- Karen Mumford
- Bob Phillips, COTPER
- Nan Kelemen, COTPER
- Stefan Weir, COTPER
- Jimmie Stephens, Chief Science Officer, CDC
- Lee Sanderson, PhD, NIOSH, CDC
- Jan Nicholson, CCID, CCD
- Stephanie Ostrawski, COTPER
- Sonya Hutchens, MD, OCPHP, CDC
- Catherine Chow, COTPER

Public Participants

- Wayne Wells, MD Harris Consultants, Inc. Atlanta, GA

Attachment 2 Acronyms

| | |
|---------------------|---|
| ADS | Associate Director for Science |
| AHRC | Atlanta Human Resource Center (HHS) |
| APHIS | Animal and Plant Health Inspection Service (USDA) |
| APHL | Association of Public Health Laboratories |
| ASPH | Association of Schools of Public Health |
| ASPR | Assistant Secretary for Preparedness and Response (HHS) |
| ASTHO | Association of State and Territorial Health Officers |
| ATSDR | Agency for Toxic Substances and Disease Registry (CDC) |
| BARDA | Biomedical Advanced Research and Development Authority |
| BSC | Board of Scientific Counselors |
| BSL-4 | Biosafety Level 4 (high containment deadly pathogens laboratory) |
| BCU | Biosurveillance Coordination Unit (CDC) |
| CA | Cooperative Agreement |
| CBRNE | Chemical, Biological, Radiological, Nuclear, and Explosive agents |
| CCID | Coordinating Center for Infectious Diseases (CDC) |
| CCEHIP | Coordinating Center for Environmental Health and Injury Prevention (CDC) |
| CDC | Centers for Disease Control and Prevention |
| CEFO | Career Epidemiology Field Officer (CDC) |
| CJIS | Criminal Justice Information Services |
| CoCHIS | Coordinating Center for Health Information and Service (CDC) |
| CoCHP (CCHP) | Coordinating Center for Health Promotion (CDC) |
| COGH | Coordinating Office for Global Health (CDC) |
| COOP | Continuity of Operations Plan or Continuation of Operation Plan |
| COP | Common Operating Picture |
| COTPER | Coordinating Office for Terrorism Preparedness and Emergency Response (CDC) |
| CPHP | Centers for Public Health Practice |
| CRI | Cities Readiness Initiative |
| CSTE | Council of State and Territorial Epidemiologist |
| DBS | Division of Business Services (CDC) |
| DCIR | Director's Critical Information Requirements (CDC) |
| DDS | Deputy Director of Science |
| DEO | Division of Emergency Operations (CDC) |
| DEOC | Director's Emergency Operation Center (CDC) |
| DFO | Designated Federal Official |
| DHS | The U.S. Department of Homeland Security |
| DHHS | The U.S. Department of Health and Human Services |
| DOD | Department of Defense also DoD |
| DOJ | Department of Justice |
| DSAT | Division of Select Agents and Toxins (CDC) |
| DSLRL | Division of State and Local Readiness (CDC) |
| DSNS | Division of Strategic National Stockpile (CDC) |
| ECO | Enterprise Communications Office (CDC) |
| EIS | Epidemic Intelligence Service (CDC) |
| ELR | Electronic Lab Reporting |
| EOC | Emergency Operations Center (CDC) |
| Epi-X | Epidemic Information Exchange |
| EPMIS | Extramural Program Management Information System |
| EPO | Epidemiology Program Office (CDC) |



Acronyms

| | |
|----------------|---|
| ERT | Emergency Response Team |
| ERT-N | (National) Emergency Response Team |
| ESF | Emergency Support Function (generally followed by function #) |
| FACA | Federal Advisory Committee Act |
| FAO | Funding Opportunity Announcement |
| FECC | Federal Emergency Communications Coordinator |
| FEMA | Federal Emergency Management Agency (DHS) |
| FOIA | Freedom of Information Act |
| FRN | Federal Register Notice |
| GAO | General Accounting Office |
| GIS | Geographic Information System |
| GSA | General Services Administration |
| HAN | Health Alert Network |
| HHS | Health and Human Services |
| HRSA | Health Resources and Services Administration |
| HSAB | Health and Safety Advisory Board |
| HSIN-CI | Homeland Security Information Network-Critical Infrastructure |
| HSPD-21 | Homeland Security Presidential Directive-21 |
| IAEA | International Atomic Energy Agency |
| IAG | Interagency Agreement also IAA - Interagency Agreement |
| ICP | Incident Command Post |
| ICS | Incident Command System |
| IG | Inspector General |
| IMS | Incident Management System |
| IOM | Institute of Medicine |
| IRCT | Incident Response Coordination Team |
| JTTF | Joint Terrorism Task Force |
| LNO | Liaison Officer |
| LRN | Laboratory Response Network |
| LOPR | Learning Office for Preparedness and Response (CDC) |
| MASO | Management Analysis and Services Office (CDC) |
| MMWR | Morbidity and Mortality Weekly Report (CDC) |
| MOO | Management Operations Officer |
| MRE | Meals Ready-to-Eat |
| NAHLN | National Animal Health Laboratory |
| NALBOH | National Association of Local Boards of Health |
| NAPHSIS | National Association for Public Health Statistics and Information Systems |
| NAS | National Academy of Sciences |
| NBIC | National Biosurveillance Integration Center (DHS) |
| NCBDDD | National Center on Birth Defects and Developmental Disabilities (CDC) |
| NCPDCID | National Center for Preparedness Detection and Control of Infectious Diseases (CDC) |
| NCCDPHP | National Center for Chronic Disease Prevention & Health Promotion (CDC) |
| NCEH | National Center for Environmental Health (CDC) |
| NCHM | National Center for Health Marketing (CDC) |
| NCHS | National Center for Health Statistics (CDC) |
| NCHSTP | National Center for HIV, STD, and TB Prevention (CDC) |
| NCID | National Center for Infectious Diseases (CDC) |
| NCIPC | National Center for Injury Prevention and Control (CDC) |



Acronyms

| | |
|----------------|--|
| NCIRD | National Center for Immunization and Respiratory Diseases (CDC) |
| NCPHI | National Center for Health Informatics (CDC) |
| NCTC | National Counterterrorism Center |
| NCZVED | National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CDC) |
| NDMS | National Disaster Medical System |
| NECC | National Emergency Coordination Center (FEMA) |
| NEDSS | National Electronic Disease Surveillance System |
| NEIS | National Earthquake Information Service |
| NERRTC | National Emergency Response & Rescue Training Center (“nertsy”) |
| NETSS | National Electronic Telecommunications Surveillance System |
| NICC | National Infrastructure Coordinating Center |
| NIH | National Institutes of Health |
| NIOSH | National Institute for Occupational Safety and Health (CDC) |
| NJTTF | National Joint Terrorism Task Force |
| NLTN | National Laboratory Training Network |
| NNDSS | National Notifiable Diseases Surveillance Systems |
| NRCC | National Response Coordination Center |
| NRP | National Response Plan |
| NOC | National Operations Center (DHS) |
| NOES | National Occupational Exposure Survey |
| NORAD | North American Aerospace Defense Command |
| NSAR | National Select Agent Registry |
| NVPO | National Vaccine Program Office |
| OCIIE | Office of Critical Information Integration and Exchange |
| OD | Office of the Director |
| ODP | Office of Domestic Preparedness |
| OEA | Organizational Excellence Assessment |
| OEP | Office of Emergency Preparedness |
| OET | Office of Emergency Transportation |
| OGDP | Office of Genomics and Disease Prevention (CDC) |
| OGH | Office of Global Health (CDC) |
| OHS | Office of Health and Safety (CDC) |
| OMEB | Organic Methods Evaluation Branch (OSHA) |
| OMS | Outbreak Management System |
| OMSPH | Office of Medicine, Science, and Public Health |
| OPPE | Office of Program Planning and Evaluation (CDC) |
| OPR | Office of Preparedness and Response (HHS) |
| OSEP | Office of Security and Emergency Preparedness (CDC) |
| OSHA | Occupational Safety and Health Administration |
| OTC | Over-the-Counter (referring to medications not requiring prescription) |
| OWCD | Office of Workforce and Career Development (CDC) |
| PAHPA | Pandemic and All Hazards Preparedness Act (PL 109-417) |
| PDW | Preparedness Data Warehouse |
| PHEMCE | Public Health Emergency Medical Countermeasures Enterprise (HHS) |
| PHLIP | Public Health Lab Interoperability Program |
| PHPPO | Public Health Practice Program Office (CDC) |
| PHTEA | Public Health Threats and Emergencies Act (PL 106-505) |
| POETE | Planning, Organization, Equipment, Training, Exercise |
| PSB-Ext | Program Services Branch – Extramural Branch |



Acronyms

| | |
|-------------------|---|
| PWMS | Preparedness Workforce Management System (CDC) |
| RCC | Regional Coordination Center |
| RRCC | Regional Response Coordination Center |
| SAs | Select Agents |
| SAP | Select Agent Program |
| SGE | Special Government Employee |
| SIO | Strategy and Innovation Office (CDC) |
| SIOC | Strategic Information & Operations Center |
| SME | Subject Matter Expert |
| SMO | Senior Management Official |
| SNS | Strategic National Stockpile (CDC) |
| SOC | Secretaries Operations Center (HHS) |
| SPAR-x | Countermeasure Surveillance, Preparedness and Response System |
| SPHPO | Science and Public Health Practice Office (CDC) |
| TAC | Technical Advisory Committee |
| TARU | Technical Advisory Response Unit (CDC) |
| USDA | United States Department of Agriculture |
| USPHS | United States Public Health Service |
| USNORTHCOM | U.S. Northern Command |
| VOAD/NVOAD | (National) Volunteer Organizations Active in Disaster |
| WCDO | Workforce and Career Development Office (CDC) |
| WISQARS | Web-based Injury Statistics Query and Reporting System |

